

Wisconsin
Chapter HFS 157- Radiation Protection
Regulatory Guide

July 2003

Guidance for Self-Shielded Irradiators

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PPH 45048 (07/03)

EXECUTIVE SUMMARY

Wisconsin Regulatory Guides (WISREGS) are issued to describe and make available to the applicant or licensee, acceptable methods of implementing specific parts of **Wisconsin Administrative Code, Chapter HFS 157 ‘Radiation Protection,’** to delineate techniques used by Department of Health and Family Services (DHFS) staff in evaluating past specific problems or postulated accidents, and to provide guidance to applicants or licensees. WISREGS are not substitutes for **Chapter HFS 157 ‘Radiation Protection,’** therefore compliance with them is not required. Methods and solutions different from those set forth in this guide will be acceptable if they provide a basis for the Department of Health and Family Services (DHFS), Radiation Protection Section to determine if a radiation protection program meets the current rule and protects public health and safety.

Comments and suggestions for improvements in this WISREG are encouraged. This WISREG will be revised, as appropriate, to accommodate comments and to reflect new information or experience. Comments should be sent to **Department of Health and Family Services, Radiation Protection Section, P.O. Box 2659, Madison, WI 53701-2659.**

To request copies of this guide (which may be reproduced) call DHFS, Radiation Protection Section at (608) 267-4797 or for an electronic copy go to our web site at:
http://dhfs.wisconsin.gov/dph_beh/RadioactiveMat/IndexRM.htm.

This WISREG “Guidance for Self Shielded Irradiator Devices” has been developed to streamline the application process for a self shielded irradiator license. A copy of the application DPH form 45014 “*Application for Radioactive Material License Authorizing the Use of Self Shielded Irradiator Devices* ” is located in **Appendix A** of this guide.

Appendix D through Q provides examples, models, procedures and additional information that can be used when completing the application.

It typically takes 60-90 days for a license to be processed and issued if the application is complete. When submitting the application be sure to Include the appropriate application fee listed in **HFS 157.10** for a Self-Shielded Irradiator.

In summary, the applicant will need to do the following to submit an application for a Self Shielded Irradiator license:

- Use this regulatory guide to prepare the application DPH form 45014, “*Application for Radioactive Material License Authorizing the Use of Self Shielded Irradiator Devices*” (**Appendix A**).
- Complete the application DPH form 45014, “*Application for Radioactive Material License Authorizing the Use of Self Shielded Irradiator Devices*” (**Appendix A**). See ‘Contents of Application’ of the guide for additional information.
- Include any additional attachments.
 - All supplemental pages should be on 8 ½” x 11” paper.
 - Please identify all attachments with the applicant’s name and license number (if a renewal).
- Avoid submitting proprietary information unless it is absolutely necessary.
- Submit an original signed application along with attachments (if any) and if possible a copy on a diskette or CD (Microsoft Word is preferred).
- Submit the application fee.
- Retain one copy of the licensee application and attachments (if any) for your future reference. You will need this information because the license will require that radioactive material be possessed and used in accordance with statements, representation, and procedures provided in the application and supporting documentation.

If you have any questions about the application process please contact DHFS, Radiation Protection Section at (608) 267-4797.

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ABBREVIATIONS

| | |
|------------------|---|
| ALARA | as low as is reasonably achievable |
| ANSI | American National Standards Institute |
| AU | authorized user |
| bkg | background |
| Bq | Becquerel |
| CaF ₂ | calcium fluoride |
| CDE | committed dose equivalent |
| CEDE | committed effective dose equivalent |
| CFR | Code of Federal Regulations |
| Ci | Curie |
| CD-ROM | compact disc-read only memory |
| C/kg | coulomb/kilogram |
| Co-60 | cobalt-60 |
| cpm | counts per minute |
| Cs-137 | cesium-137 |
| d | Day |
| DHFS | Department of Health and Family Services |
| DOE | United States Department of Energy |
| DOT | United States Department of Transportation |
| EDE | effective dose equivalent |
| FDA | United States Food and Drug Administration |
| ft | Foot |
| GBq | Gigabecquerel |
| G-M | Geiger-Mueller |
| GPO | Government Printing Office |
| hr | Hour |
| IN | Information Notice |
| IP | Inspection Procedure |
| kg | kilogram |
| LiF | lithium fluoride |
| m | meter |
| MBq | megabecquerel |
| mCi | millicurie |
| MeV | million electron volt |
| mGy | milligray |
| mo | Month |
| MOU | memorandum of understanding |
| mR | milliroentgen |
| mrem | millirem |
| mSv | millisievert |
| NCRP | National Council on Radiation Protection and Measurements |
| NIST | National Institute of Standards and Technology |
| NMSS | Office of Nuclear Material Safety and Safeguards |
| NRC | United States Nuclear Regulatory Commission |
| NTIS | National Technical Information Service |
| NVLAP | National Voluntary Laboratory Accreditation Program |
| OSP | Office of State Programs |

| | |
|----------|---|
| P&GD | Policy and Guidance Directive |
| QA | quality assurance |
| R | roentgen |
| Rev. | revision |
| RG | Regulatory Guide |
| RQ | reportable quantities |
| RSO | radiation safety officer |
| SDE | shallow-dose equivalent |
| Sr-90 | strontium-90 |
| SFPO | Spent Fuel Project Office |
| SI | International System of Units (abbreviated SI from the French Le Systeme Internationale d'Unites) |
| SSD | sealed source and device |
| std | Standard |
| Sv | Sievert |
| TAR | technical assistance request |
| TBq | Terabecquerel |
| TEDE | total effective dose equivalent |
| TI | transportation index |
| TLD | thermoluminescent dosimeters |
| URL | uniform resource locator |
| U. S. C. | United States Code |
| USDA | United States Department of Agriculture |
| WISREG | Wisconsin Regulatory Guidance |
| wk | Week |
| yr | year |

PURPOSE OF GUIDE

This document provides guidance to an applicant or licensee in preparing a self-shielded irradiator license application as well as DHFS criteria for evaluating a self-shielded irradiator license application.

Note: Irradiators subject to the requirements of **Chapter HFS 157 ‘Radiation Protection’ Subchapter VII, ‘Radiation Safety Requirements for Irradiators’** are not discussed in this guide.

This WISREG is not intended to address the research and development or the commercial aspects of manufacturing, distribution, and service of self-shielded irradiators and their associated sources.

Within this document, the phrases or terms, "self-shielded irradiator," "self-contained irradiators," or "irradiators" are used interchangeably.

Irradiators are used for a variety of purposes in research, industry, and other fields. Typical uses are:

- Irradiating blood or blood products
- Sterilizing or reducing microbes in medical and pharmaceutical supplies
- Preserving foodstuffs
- Studying radiation effects
- Synthesizing and modifying chemicals and polymers
- Eradicating insects through sterile male release programs
- Calibrating thermoluminescent dosimeters (TLDs).

The American National Standards Institute (ANSI) has developed and published safety standards for gamma irradiators. In determining basic safety requirements, ANSI divided all gamma irradiators into four general categories. This report deals with the type of irradiator discussed in ANSI Standard N433.1, "Safe Design and Use of Self-Contained, Dry Source Storage Gamma Irradiators (Category I)."

Note: Copies of this standard may be ordered electronically at <http://www.ansi.org> or by writing to ANSI, 1430 Broadway, New York, NY 10018. Copies are also available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161 (1-800-533-6847

This guide also uses the same definition of a self-shielded irradiator as the ANSI definition for a Category I irradiator: "[a]n irradiator in which the sealed source(s) is completely contained in a dry container constructed of solid materials, the sealed source(s) is shielded at all times, and human access to the sealed source(s) and the volume(s) undergoing irradiation is not physically possible in its designed configuration."

Depending on the design, the radiation source within the irradiator may be in a fixed position or may be movable. In the latter case, interlocks are used to ensure that the source does not move into a position that, during normal use of the irradiators, may cause a radiation hazard to any individual. Bypassing or failure of an interlock could cause persons to be exposed to high levels of radiation.

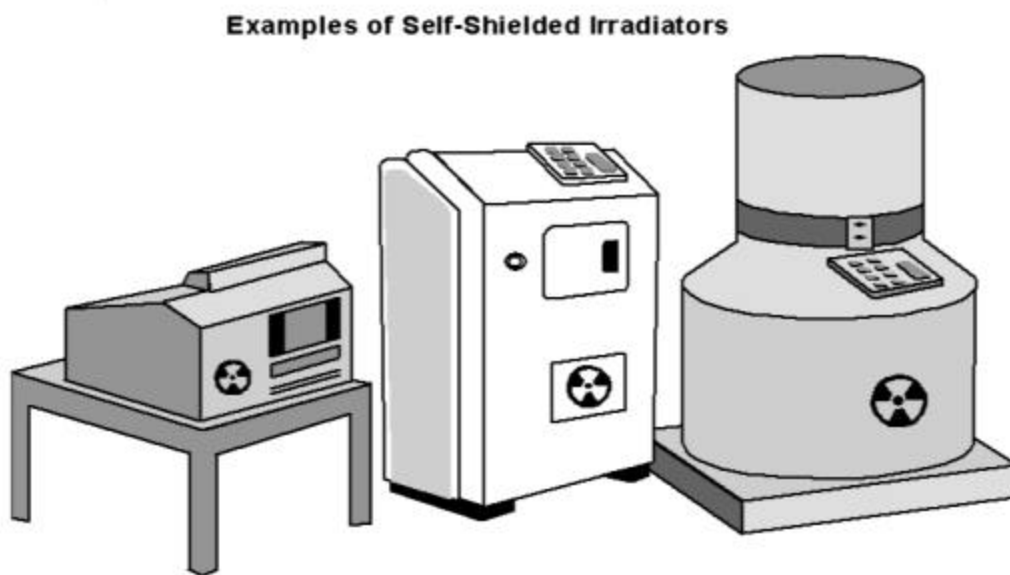


Figure 1. *Types of Irradiators.* The irradiator on the far left is used to calibrate dosimetry devices, while the other two units are research irradiators.

Self-shielded irradiators typically contain several hundred to several thousand terabecquerels (TBq) (or curies (Ci)) of cesium-137 (Cs-137) or cobalt-60 (Co-60) and range in weight from several hundred to several thousand kilograms (kg) (or pounds). Other irradiators contain megabecquerel (MBq) (or millicurie (mCi)) quantities of strontium-90 (Sr-90), a beta emitter, and are used primarily for thermoluminescent dosimeter (TLD) calibration.

This document identifies the information needed to complete DPH Form 45014 '*Application for a Radioactive Material License Authorizing the Use of Self Shielded Irradiators.*'

The format within this document for each item of technical information is as follows:

- Rule--references **Chapter HFS 157 ‘Radiation Protection’** requirements applicable to the item;
- Criteria--outlines the criteria used to judge the adequacy of the applicant's response;
- Discussion--provides additional information on the topic sufficient to meet the needs of most readers; and
- Response from Applicant--provides the applicants suggested response(s), offers the option of an alternative reply, or indicates that no response is needed on that topic during the licensing process.

Notes and References are self-explanatory and may not be found for each item on DPH Form 45014 “*Application for Radioactive Material License Authorizing the Use of Self Shielded Irradiator Devices*”. DPH Form 45014 “*Application for Radioactive Material License Authorizing the Use of Self Shielded Irradiator Devices*” may not have sufficient space for applicants to provide full response; as indicated on the form, the answers to those items are to be provided on separate sheets of paper and submitted with the completed DPH Form 45014, ‘*Application for a Radioactive Material License Authorizing the Use of Self Shielded Irradiators.*’ **Appendices D through Q** contain additional information on various radiation safety topics.

In this document, dose or radiation dose means absorbed dose, dose equivalent, effective dose equivalent (EDE), committed dose equivalent (CDE), committed effective dose equivalent (CEDE), or total effective dose equivalent (TEDE). These terms are defined in **Chapter HFS 157, Subchapter I, ‘General Provisions.’** Rem, and its SI equivalent Sievert (1 rem = 0.01 Sievert (Sv)), are used to describe units of radiation exposure or dose. This is because **Chapter HFS 157, Subchapter III, ‘Standards for Protection from Radiation.’** sets dose limits in terms of rem, not rad or roentgen (R), and the sealed sources used in irradiators emit beta and gamma rays, for which the quality factor is 1; a useful rule of thumb is an exposure of 1 roentgen is equivalent to an absorbed dose of 1 rad and dose equivalent of 1 rem.

WHO REGULATES AT FEDERAL FACILITIES IN WISCONSIN?

In the special situation of work at federally-controlled sites in Wisconsin, it is necessary to know the jurisdictional status of the land to determine whether Nuclear Regulatory Commission (NRC) or DHFS has regulatory authority. The NRC has regulatory authority over land determined to be under “exclusive federal jurisdiction,” while DHFS has jurisdiction over non-exclusive federal jurisdiction land (see **Table 1**). Applicants and licensees are responsible for finding out, in advance, the jurisdictional status of the specific areas where they plan to conduct licensed operations. DHFS recommends that applicants and licensees ask their local contacts for the federal agency controlling the site (e.g., contract officer, base environmental health officer, district office staff) to help determine the jurisdictional status of the land and to provide the information in writing, so that licensees can comply with NRC or DHFS regulatory requirements, as appropriate.

Table 1 Who Regulates the Activity?

| Applicant and Proposed Location of Work | Regulatory Agency |
|--|--------------------------|
| Federal agency regardless of location (except that Department of Energy [DOE] and, under most circumstances, its prime contractors are exempt from licensing [10 CFR 30.12]) | NRC |
| Non-federal entity in non-Agreement State, U.S. territory, or possession | NRC |
| Non-federal entity in WI at non-federally controlled site | DHFS |
| Non-federal entity in WI at federally-controlled site <i>not</i> subject to exclusive Federal jurisdiction | DHFS |
| Non-federal entity in WI at federally-controlled site subject to exclusive federal jurisdiction | NRC |

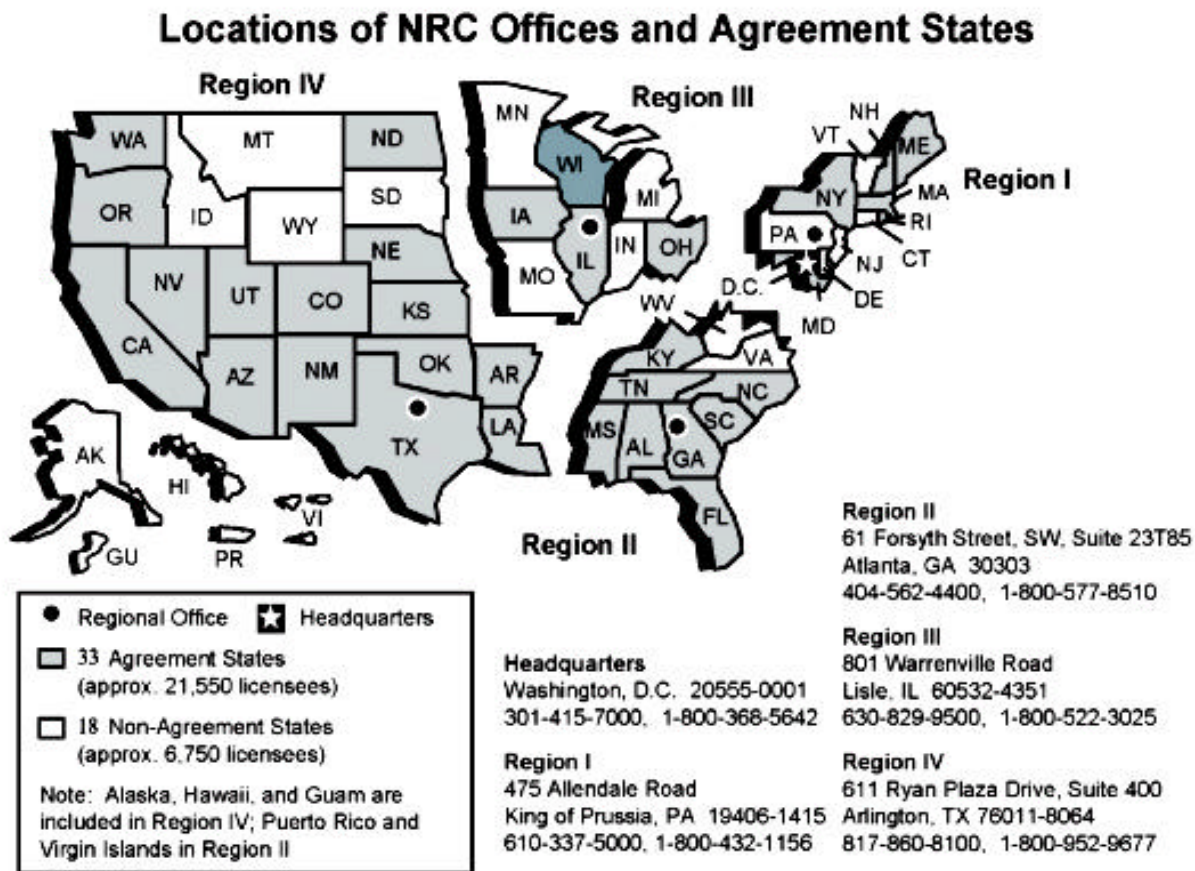


Figure 2. U.S. Map *Location of NRC Offices and Agreement States.*

Reference: A current list of Agreement States (States that have entered into agreements with the NRC that give them the authority to license and inspect radioactive material used or possessed within their borders), (including names, addresses, and telephone numbers of responsible officials) may be obtained upon request from NRC's Regional Offices. NRC Office of State and Tribal Programs (STP) also provides the current list of Agreement States which can be found at <http://www.hsr.gov/NRC>.

MANAGEMENT RESPONSIBILITY

DHFS recognizes that effective radiation safety program management is vital to achieving safe and compliant operations. DHFS also believes that consistent compliance with **Chapter HFS 157 ‘Radiation Protection’** provides reasonable assurance that licensed activities will be conducted safely. Through its experience, DHFS has found that effective management has been shown to be key to a well-run radiation safety program. Management refers to a senior-level manager who has responsibility for overseeing licensed activities.

To ensure adequate management involvement, a management representative must sign the submitted application acknowledging management’s commitments and responsibility for all the following:

- Radiation safety, security and control of radioactive materials, and compliance with **Chapter HFS 157 ‘Radiation Protection’**;
- Completeness and accuracy of the radiation safety records and all information provided to DHFS;
- Knowledge about the contents of the license and application;
- Committing adequate resources (including space, equipment, personnel, time and if needed, contractors) to the radiation protection program to ensure that public and worker safety is protected from radiation hazards and compliance with the rule is maintained; and
- Selecting and assigning a qualified individual to serve as the Radiation Safety Officer (RSO) for their licensed activities.

APPLICABLE RULE

It is the applicant's or licensee's responsibility to obtain, read and follow **Chapter HFS 157 'Radiation Protection'**.

The following subchapters of **Chapter HFS 157 "Radiation Protection"** contain requirements applicable to self shielded irradiators licensees:

- Subchapter I: General Provisions
- Subchapter II: Licensing of Radioactive Material
- Subchapter III: Standards for Protection from Radiation
- Subchapter X: Notices, Instructions and Reports to Workers
- Subchapter XI: Inspection By the Department
- Subchapter XII: Enforcement
- Subchapter XIII: Transportation

To request copies of the above documents, call Department of Health and Family Services (DHFS), Radiation Protection Section at (608) 267-4797 or for electronic copy go to our web site at: http://dhfs.wisconsin.gov/dph_beh/RadioactiveMat/IndexRM.htm.

HOW TO FILE

PAPER APPLICATION

Applicants for a materials license should do the following:

- Be sure to use the current guidance from DHFS in preparing an application.
- Complete DPH Form 45014 “*Application for Radioactive Material License Authorizing the Use of Self Shielded Irradiator Devices*” (**Appendix A**).
- For each separate sheet, other than submitted with the application, identify and key it to the item number on the application, or the topic to which it refers.
- Submit all documents on 8 ½ x 11 – inch paper.
- Avoid submitting proprietary information unless it is absolutely necessary.
- Submit an original, signed application.
- Retain one copy of the license application for your future reference.

Deviations from the suggested wording of responses as shown in this WISREG or submission of alternative procedures will require a more detailed review.

Personal employee information, i.e., home address, home telephone number, Social Security Number, date of birth, and radiation dose information, should not be submitted unless specifically requested by DHFS.

WHERE TO FILE

Applicants wishing to possess or use radioactive material in Wisconsin are subject to the requirements of **Chapter HFS 157 ‘Radiation Protection’** and must file a license application with:

*Department of Health and Family Services
Radiation Protection Section
P.O. Box 2659
Madison, WI 53701-2659*

LICENSE FEES

The appropriate fee must accompany each application or license amendment request. Refer to ***HFS 157.10*** to determine the amount of the fee. DHFS will not issue the new license prior to fee receipt. Once the application review has begun, no fees will be refunded. Application fees will be charged regardless of DHFS's disposition of an application or the withdrawal of an application.

Licensees are also subject to annual fees; refer to ***HFS 157.10***.

Direct all questions about DHFS's fees or completion of **Item 11** of DPH Form 45014, "*Application for Radioactive Material License Authorizing the Use of Self Shielded Irradiator Devices*" (**Appendix A**) to DHFS, Radiation Protection Section at (608) 267-4797.

CONTENTS OF AN APPLICATION

Item 1: License Action Type

On the application check the appropriate box and list the license number for renewals and amendments.

Response from Applicant:

| | | |
|---|---|---|
| Item 1 Type Of Application (Check one box) | | |
| <input type="checkbox"/> New License | <input type="checkbox"/> Renewal License Number _____ | <input type="checkbox"/> Amendment License Number _____ |

Item 2: Applicant's Name and Mailing Address

List the legal name of the applicant's corporation or other legal entity with direct control over use of the radioactive material; a division or department within a legal entity may not be a licensee. An individual may be designated as the applicant only if the individual is acting in a private capacity and the use of the radioactive material is not connected with employment in a corporation or other legal entity. Provide the mailing address where correspondence should be sent. A Post Office box number is an acceptable mailing address.

Notify DHFS of changes in mailing address.

Response from Applicant:

| |
|--|
| Item 2 Name And Mailing Address Of Applicant: |
| |
| Applicant's Telephone Number (Include area code): |
| |

Note: DHFS must be notified before control of the license is transferred or when bankruptcy proceedings have been initiated. See below for more details. NRC *Information Notice (IN) 97-30, "Control of Licensed Material during Reorganizations, Employee-Management*

Disagreements, and Financial Crises," dated June 3, 1997, discusses the potential for the security and control of licensed material to be compromised during periods of organizational instability.

Timely Notification of Transfer of Control

Rule: *HFS 157.13(10)*

Criteria: Licensees must provide full information and obtain DHFS's *prior written consent* before transferring control of the license, or, as some licensees call it, "transferring the license."

Discussion: Transferring control may be the result of mergers, buyouts, or majority stock transfers. Although it is not DHFS's intent to interfere with the business decisions of licensees, it is necessary for licensees to obtain prior DHFS written consent before the transaction is finalized. This is to ensure the following:

- Radioactive materials are possessed, used, or controlled only by persons who have valid DHFS, NRC or Agreement State licenses
- Materials are properly handled and secured
- Persons using these materials are competent and committed to implementing appropriate radiological controls
- A clear chain of custody is established to identify who is responsible for disposition of records and licensed material
- Public health and safety are not compromised by the use of such materials.

Notification of Bankruptcy Proceedings

Rule: *HFS 157.13(10)*

Criteria: Within 10 days following filing of voluntary or involuntary petition for bankruptcy for or against a licensee, the licensee must notify DHFS, in writing, identifying the bankruptcy court in which the petition was filed and the date of filing.

Discussion: Even though a licensee may have filed for bankruptcy, the licensee remains responsible for all regulatory requirements. DHFS needs to know when licensees are in

bankruptcy proceedings in order to determine whether all licensed material is accounted for and adequately controlled and whether there are any public health and safety concerns (e.g., contaminated facility). DHFS shares the results of its determinations with other involved entities (e.g., trustee) so that health and safety issues can be resolved before bankruptcy actions are completed.

References: INs are available at NRC’s web site, <http://www.nrc.gov>, under “Electronic Reading Room,” then “Document Collections,” then “Generic Communications” for IN’s or “NUREG –Series Publications” for NUREGS.

Item 3: Person to Be Contacted about this Application

Identify the individual who can answer questions about the application and include his or her telephone number. This is typically the proposed RSO, unless the applicant has named a different person as the contact. DHFS will contact this individual if there are questions about the application.

Notify DHFS if the contact person or his or her telephone number changes so that DHFS can contact the applicant or licensee in the future with questions, concerns, or information. This notice is for "information only" and does not require a license amendment or a fee.

Response from Applicant:

Item 3 Person To Contact Regarding Application:

Contact's Telephone Number (Include area code):

Item 4: Address(es) Where Licensed Material Will Be Used or Possessed

Specify the street address, city, and state or other descriptive address (e.g., on Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Anytown, WI) for each facility. The descriptive address should be sufficient to allow a DHFS inspector to find the facility location. **A Post Office Box address is not acceptable.**

A DHFS-approved license amendment is required before locating an irradiator at an address not already listed on the license or at a new room location, whether that irradiator is an additional unit or a relocation of an existing unit.

Being granted a DHFS license does not relieve a licensee from complying with other applicable Federal, State, or local regulations (e.g., local zoning requirements; a local ordinance requiring registration of a radiation-producing device).

Response from Applicant:

| Item 4 Addresses Where Licensed Material Will Be Used or Possessed (Do not use Post Office Box): | |
|--|--------------------------------------|
| Address | Telephone Number (Include area code) |
| Address | Telephone Number (Include area code) |
| Address | Telephone Number (Include area code) |

Note: As discussed later under "Financial Assurance and Record Keeping for Decommissioning," licensees do need to maintain permanent records on where licensed material was used or stored while the license was in force. This is important for making future determinations about the release of these locations for unrestricted use (e.g., before the license is terminated). For self-shielded irradiator licensees, acceptable records are sketches or written descriptions of the specific locations where each irradiator is used or stored and any information relevant to damaged devices or leaking radioactive sources.

Item 5: Radiation Safety Officer (RSO)

Rule: *HFS 157.13(2)*

Criteria: RSOs must have adequate training and experience. Successful completion of training as described in **Appendix G** is evidence of adequate training and experience.

Discussion: The person responsible for the radiation protection program is called the Radiation Safety Officer, or RSO. The RSO needs independent authority to stop operations that he or she considers unsafe. He or she must have sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radioactive materials are used in a safe manner. Typical RSO duties are illustrated in **Figure 3** and described in **Appendix H**. DHFS requires the name of the RSO on the license to ensure that licensee management has always identified a responsible, qualified person and that the named individual knows of his or her designation as RSO.

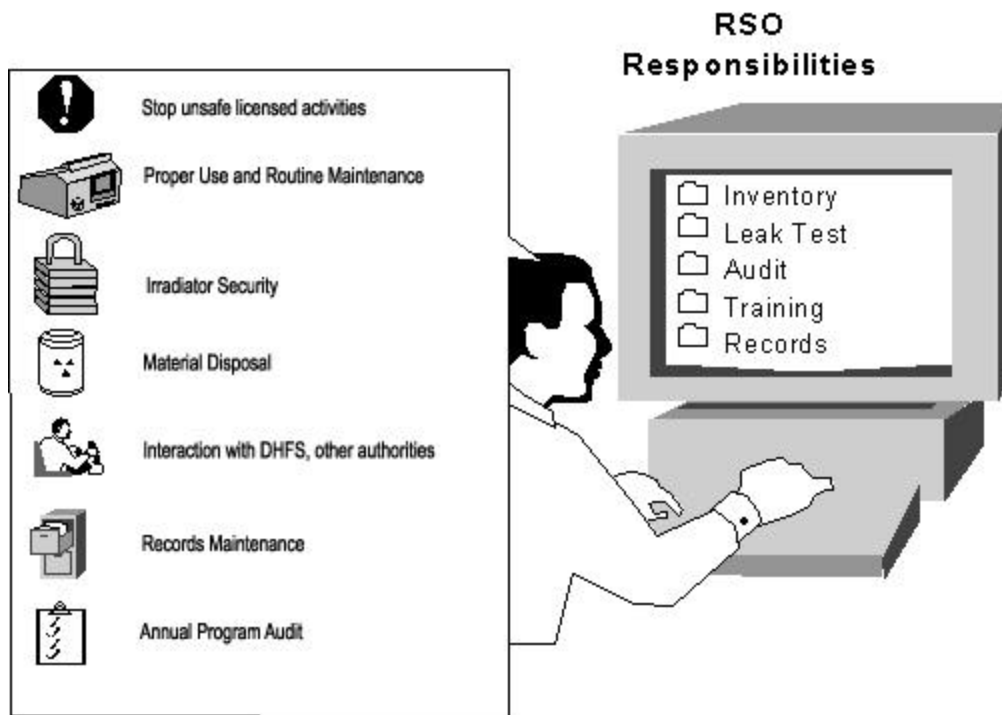


Figure 3. RSO Responsibilities. *Typical duties and responsibilities of RSOs.*

Response from Applicant:

Item 5. Radiation Safety Officer (RSO) (Check one box and attach evidence of training and experience)

Name: _____ Telephone Number (Include area code): _____

- ☐ Before obtaining radioactive material, the proposed RSO will have successfully completed training as described in Appendix G of 'WISREG 'Guidance For Self Shielded Irradiators'. Before being named as the RSO, future RSOs will have successfully Completed training as described in Appendix G of WISREG 'Guidance For Self Shielded Irradiators.'

OR

- ☐ Alternative information demonstrating that the proposed RSO is qualified by training and experience is attached. Before being named as the RSO, future RSOs will have successfully completed training as described in Appendix G of WISREG 'Guidance For Self Shielded Irradiators.'

Item 6: Authorized Users (AUs)

Rule: *HFS 157.13(2)*

Criteria: Authorized users (AUs) must have adequate training and experience. Successful completion of training as described in **Appendix G** is evidence of adequate training and experience.

Discussion: An AU is a person whose training and experience meet DHFS criteria, who is named either explicitly or implicitly on the license, and who uses or directly supervises the use of licensed material. AUs must ensure the proper use, security, and routine maintenance of self-shielded irradiators containing licensed material. They must have appropriate training to provide reasonable assurance that they will use the irradiator safely, maintain security of and access to the irradiator, and respond appropriately to accidents and malfunctions.

An AU is considered to be supervising the use of licensed material when he or she directs personnel in operations involving the material. Although the AU may delegate specific tasks to supervised users (e.g., maintaining records), he or she is still responsible for safe use of licensed material.

Response from Applicant:

Item 6 Authorized Users (Check one box)

☐ Before using radioactive material, authorized users will have received training as described in Appendix G in WISREG 'Guidance for Self Shielded Irradiators.'

OR

☐ A description of the training and experience for proposed authorized users is attached.

Item 6.1: Training for Individuals Working in or Frequenting Restricted Areas (Instructions to Occupationally Exposed Workers and Ancillary Personnel)

Rule: *HFS 157.88(1-3); HFS 157.28(1)(a&b); HFS 157.89(4)(b); HFS 157.03; HFS 157.05(2); HFS 157.13(2)*

Criteria: Individuals working with, as well as in the vicinity of, a self-shielded irradiator must have adequate training and experience. For those individuals who are not AUs yet work in the vicinity of a self-shielded irradiator and, in the course of employment, are likely to receive in a year an occupational dose of radiation over 1 millisievert (mSv) (100 millirem (mrem)), the licensee must provide training as required by ***HFS 157.88(2)***. The extent of this training must be commensurate with potential radiological health protection problems present in the work place.

Discussion: Individuals, other than AUs (e.g., biomedical engineers), may perform routine maintenance on irradiators. However, they must be trained in radiation safety and in the irradiator manufacturers' operating procedures, or they must work under the supervision and in the direct physical presence of someone who has this training.

Some licensees may have specific individuals trained to perform installations, relocations, non-routine maintenance, or repairs. Authorizations for these functions are separate from those for an AU or an individual who performs routine maintenance and will be specifically stated in a license condition. **Appendix I** contains training for individuals who will conduct non-routine maintenance.

A licensee may recognize that some individuals (e.g., housekeeping staff), although not likely to receive doses over 1 mSv (100 mrem), should receive training to ensure adequate security and control of licensed material. Licensees may provide these individuals with training commensurate with their involvement with licensed material. For example, housekeeping staff may receive training on the nature and location of the irradiator and the meaning of the radiation symbol, and instructions not to touch the irradiator and to remain out of the room if the irradiator door is open.

Item 7: Radioactive Material

Sealed Radioactive Material

Rule: *HFS 157.13(1); HFS 157.13(2)*

Criteria: Applicants must provide the manufacturer's (or distributor's) name and model number for each requested sealed source and device. Licensees will be authorized to possess and use only those sealed sources and devices specifically approved or registered by DHFS, NRC or an Agreement State.

Discussion: NRC or an Agreement State performs a safety evaluation of self-shielded irradiators before authorizing a manufacturer (or distributor) to distribute the irradiators to specific licensees. The safety evaluation is documented in a Sealed Source and Device (SSD) Registration Certificate. Before the formalization of the SSD registration process, some older irradiators may have been specifically approved on a license. Licensees can continue to use those units specifically listed on their licenses. Applicants must provide the manufacturer's (or distributor's) name and model number for each requested sealed source and device so that DHFS can verify that they have been evaluated in an SSD Registration Certificate or specifically approved on a license.

As explained in an "Urgent Notice" with an enclosed Order, both dated July 3, 1984 (see **Appendix E**), an NRC licensee identified a malfunction that could have resulted in a radiation overexposure. The malfunction involved an interlock mechanism which would have failed to prevent a shielded door from being opened after the source had moved out of the shielded position. The Order, which remains in effect, modifies licenses that authorize J. L. Shepherd

Mark I or Model 81-22 irradiators. Applicants wishing to use either of these models must comply with the Order's requirements.

Consult with the proposed manufacturer (or distributor) to ensure that requested sources and devices are compatible and conform to the sealed source and device designations registered with NRC or an Agreement State. Licensees may not make any changes to the sealed source, device, or source/device combination that would alter the description or specifications from those indicated in the respective registration certificates, without obtaining DHFS's prior permission in a license amendment. Such changes may necessitate a custom registration review, increasing the time needed to process a licensing action.

SSD Registration Certificates contain sections on "Conditions of Normal Use" and "Limitation and Other Considerations of Use." These sections may include limitations derived from conditions imposed by the manufacturer (or distributor), by particular conditions of use that would reduce radiation safety of the device, or by circumstances unique to the sealed source or device. For example, working life of the device or appropriate temperature and other environmental conditions may be specified. Except as specifically approved by DHFS, licensees are required to use irradiators according to their respective SSD Registration Certificates. Accordingly, applicants may want to get a copy of the certificate and review it or discuss it with the manufacturer (or distributor).

Purpose(s) for Which Licensed Material Will Be Used

Rule: *HFS 157.13(2)*

Criteria: Proposed activity is authorized by **Chapter HFS 157 ‘Radiation Protection’**, and irradiators will be used only for the purposes for which they were designed and according to the manufacturer's (or distributor's) recommendations and instructions for use as specified in an approved SSD Registration Certificate. Uses other than those already listed must not compromise the integrity of the source or source shielding or other components of the device critical to radiation safety.

Discussion: Allowed uses normally include irradiation of blood, insects, animals, biological samples, and inanimate objects. Usually prohibited are irradiation of flammable and explosive materials which may harm the shielding or the sealed source containment, or other materials

(e.g., unsealed containers of acids or corrosive liquids) which may interfere with the safe operation of the device. Irradiation of food for commercial distribution to the public is subject to regulations of the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) and will not be discussed in this document.

Requests to irradiate items not listed or prohibited in the SSD Registration Certificate will be reviewed on a case-by-case basis. Applicants need to submit enough information to demonstrate that irradiation of the proposed items will not compromise the integrity of the source or source shielding, or other components critical to radiation safety of the device. Contact DHFS for additional case-specific guidance. Being granted a DHFS license does not relieve a licensee from complying with other applicable Federal, State, or local regulations (e.g., FDA and USDA regulations about irradiation of food for commercial distribution).

Response from Applicant:

| | |
|--|---|
| Item 7 Radioactive Material (Attach additional pages if necessary) | |
| ELEMENT AND MASS NUMBER <input type="checkbox"/> Cobalt-60 <input type="checkbox"/> Strontium-90 <input type="checkbox"/> Cesium-137 <input type="checkbox"/> Other Isotope (please specify): | CHEMICAL AND PHYSICAL FORM SEALED SOURCE |
| SEALED SOURCE MANUFACTURER OR DISTRIBUTOR AND MODEL NUMBER | DEVICE MANUFACTURER OR DISTRIBUTOR AND MODEL NUMBER |
| MAXIMUM QUANTITY (Not to exceed either the maximum activity per source or device as specified in the Sealed Source and Device Registration Certificate) | SEALED SOURCE AND DEVICE REGISTRATION SHEET NUMBER |
| INTENDED USE: | |

Note: For more information about the SSD registration process, see the current version of NUREG - 1556, Vol. 3, "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration." It can be accessed at NRC's web site, <http://www.nrc.gov>, under "Electronic Reading Room," then "Document Collections," then "Generic Communications" for IN's or "NUREG –Series Publications" for NUREGS.

Item 7.1 Financial Assurance and Recordkeeping for Decommissioning

Rule: *HFS 157.10; HFS 157.13(9)(b); HFS 157.15*

Criteria: Self-shielded irradiator licensees authorized to possess sealed sources containing radioactive material in excess of the limits specified in *HFS 157.15* must provide evidence of financial assurance for decommissioning.

Even if no financial assurance is required, licensees are required to maintain, in an identified location, decommissioning records related to structures and equipment where irradiators are used or stored and to leaking sources. Pursuant to *HFS 157.15*, licensees must transfer these records important to decommissioning to either of the following:

- The new licensee, before licensed activities are transferred or assigned according to *HFS 157.15*
- DHFS before the license is terminated.

Discussion: The requirements for financial assurance are specific to the types and quantities of radioactive material authorized on a license. Most self-shielded irradiator applicants and licensees do not need to take any action to comply with the financial assurance requirements because their total inventory of licensed material does not exceed the limits in *HFS 157.15*. The limits for typical self-shielded irradiator sealed sources are shown in **Table 2**. Applicants requesting more than one radionuclide need to use the sum of the ratios method to determine whether financial assurance is needed. See **Appendix F** for additional information.

Table 2. Minimum Inventory Quantity Requiring Financial Assurance

| Radionuclide | Activity | |
|--------------|---------------------|------------|
| | Gigabecquerel (GBq) | Curie (Ci) |
| Cs-137 | 3.7×10^6 | 100,000 |
| Co-60 | 3.7×10^5 | 10,000 |
| Sr-90 | 3.7×10^4 | 1,000 |

In most cases, a licensee would need to possess several irradiators before the financial assurance requirements would apply. Since the standard self-shielded irradiator license does not specify the

maximum number of irradiators that a licensee may possess (allowing flexibility in obtaining additional irradiators specifically authorized by the license without amending its license), it contains a condition requiring the licensee to limit its possession of self-shielded irradiators to quantities not requiring financial assurance for decommissioning.

Applicants and licensees wanting to possess self-shielded irradiators or irradiators and other licensed materials exceeding the limits in **HFS 157.15** must submit evidence of financial assurance or a decommissioning funding plan (**HFS 157.15**). NRC *Reg Guide 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72,"* dated June 1990, contains approved wording for each mechanism authorized by the regulation to guarantee or secure funds except for the Statement of Intent for government licensees. See **Appendix F** for the recommended wording for a Statement of Intent.

DHFS will authorize possession exceeding the limits shown in **Table 2** without requiring decommissioning financial assurance, for the purpose of normal source exchange for no more than 30 days.

The same rule also requires that licensees maintain records important to decommissioning in an identified location. All self-shielded irradiator licensees need to maintain records of structures and equipment where each irradiator was used or stored. As-built drawings with modifications of structures and equipment shown as appropriate fulfill this requirement. If drawings are not available, licensees shall substitute appropriate records (e.g., a sketch of the room or building, or a description of the area) concerning the specific areas and locations. If no records exist regarding structure and equipment where self-shielded irradiators were used or stored, licensees shall make all reasonable efforts to create such records based upon historical information (e.g., employee recollections). In addition, if self-shielded irradiator licensees have experienced unusual occurrences (e.g., leaking sources, other incidents that involve spread of contamination), they also need to maintain records about contamination that remains after cleanup or that may have spread to inaccessible areas.

| |
|--|
| For self-shielded irradiator licensees whose sources have never leaked, acceptable records important to decommissioning are sketches or written descriptions of the specific locations where each irradiator was used or stored. |
|--|

HFS 157.15 Requirements for Disposition of Records Important to Decommissioning

- Before licensed activities are transferred or assigned according to **HFS 157.15**, transfer to the new licensee
- OR
- Before the license is terminated, transfer records to DHFS.

References: To obtain copies of RG 3.66 and P&GD FC 90-2 (Rev. 1), "Standard Review Plan for Evaluating Compliance with Decommissioning Requirements," dated April 30, 1991 are available at NRC's web site, <http://www.nrc.gov>, under "Electronic Reading Room."

Item 8: Facilities and Equipment

Rule: *HFS 157.13(2)*

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property.

Discussion: Self-shielded irradiators incorporate many engineering features to protect individuals from unnecessary radiation exposure. These devices are usually designed for use in a laboratory environment, i.e., inside a building, protected from the weather, and without wide variations of temperature and humidity. For information to help applicants determine the location of irradiators, see the sections on the SSD Registration Certificate entitled, "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use."

For example, if a proposed location for a self-shielded irradiator is not within the conditions of normal use or the limitations of use, the applicant will need to provide adequate justification. In addition, the applicant will need to take compensatory measures (e.g., increased surveillance and maintenance) to ensure that the irradiator operates as designed and provides the intended level of protection. IN 96-35, "Failure of Safety Systems on Self-Shielded Irradiators Because of Inadequate Maintenance and Training," dated June 11, 1996, discusses an incident resulting from irradiator failure in which the lack of a climate-controlled environment (i.e., loading dock) may have accelerated the degradation of internal components leading to a failed interlock and excessive dose received by an irradiator operator.

Self-shielded irradiators vary in weight from several hundred to several thousand kilograms (pounds). Before installing an irradiator, licensees need to evaluate whether the floor in the proposed location can support the irradiator. Often licensees locate self-shielded irradiators on a ground floor. Some smaller and lighter irradiators require additional security measures to prevent unauthorized removal (e.g., locked in a room, bolted to the floor). For more information see **Item 9.6 ‘Operating and Emergency Procedures’** and **Item 9.5 ‘Public Dose.’**

The fire-resistant properties of most irradiators should provide adequate radioactive material containment and shielding integrity in most situations; however, additional protection is desirable for some situations. For example, the room housing the irradiator should be equipped with an automatically-operated fire detection and control system (sprinkler, chemical, or gas). As an alternative, the self-shielded irradiator should be located under conditions (e.g., ground floor location in fire-resistant building with little combustible material) and other controls (e.g., coordination with and training of firefighting personnel) that ensure a low level of radiation risk attributable to fires.

The applicant should identify the self-shielded irradiator location by room number and should submit drawings of the location within the facility.

Response from Applicant:

Item 8 Facilities And Equipment (Check all that apply)

- ☐ Diagrams of radioactive material area(s) of use are attached.

AND EITHER

- ☐ We will ensure that each area where a self-shielded irradiator is located corresponds to the ‘Conditions of Normal Use’ and ‘Limitations and/or Other Considerations of Use’ on the applicable irradiator’s Sealed Source and Device Registration Certificate; the floor beneath the self shielded irradiator is secured to prevent unauthorized access or removal; and each area where a self shielded irradiator is located is equipped with an automatically operated fire detection and control system (sprinkler, chemical, or gas) or the location of the area and other controls ensure a low-level radiation risk attributable to fires.

OR

- ☐ We will submit alternative information; be sure to include justification for placing an irradiator in an area that does not correspond to the ‘Conditions of Normal Use’ and the ‘Limitations and/or Other Considerations of Use.’

References: INs are available at NRC’s web site, <http://www.nrc.gov>, under “Electronic Reading Room,” then “Document Collections,” then “Generic Communications” for IN’s or “NUREG –Series Publications” for NUREGS.

Item 9: Radiation Safety Program

Item 9.1: Audit Program

Rule: *HFS 157.21; HFS 157.31(2)*

Criteria: Licensees must review the content and implementation of their radiation protection programs annually to ensure the following:

- Compliance with DHFS and DOT regulations (as applicable), and the terms and conditions of the license;
- Occupational doses and doses to members of the public are as low as is reasonably achievable (ALARA) (*HFS 157.21*); and
- Records of audits and other reviews of program content are maintained for 3 years.

Discussion: **Appendix J** contains a suggested audit program that is specific to the use of self-shielded irradiators and is acceptable to DHFS. All areas indicated in **Appendix J** may not be applicable to every licensee and may not need to be addressed during each audit. For example, licensees do not need to address areas which do not apply to their activities, and activities which have not occurred since the last audit need not be reviewed at the next audit. Generally, audits are conducted at least once every 12 months.

DHFS's emphasis in inspections is to perform actual observations of work in progress. As a part of their audit programs, applicants should consider performing unannounced audits of irradiator users to determine if, for example, Operating and Emergency Procedures are available and are being followed.

It is essential that once identified, problems be corrected comprehensively and in a timely manner; IN 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," dated May 1, 1996, provides guidance on this subject. DHFS will review the licensee's audit results and determine if corrective actions are thorough, timely, and sufficient to prevent recurrence. If violations are identified by the licensee and these steps are taken, DHFS can exercise discretion and may elect not to cite a violation. DHFS's goal is to encourage prompt identification and prompt, comprehensive correction of violations and deficiencies.

Licensees must maintain records of audits and other reviews of program content and implementation for 3 years from the date of the record. DHFS will find that audit records containing the following information to be acceptable: date of audit, name of person(s) who conducted audit, persons contacted by the auditor(s), areas audited, audit findings, corrective actions, and follow-up.

Response from Applicant:

Item 9.1 Audit Program

The applicant is not required to, and should not, submit its audit program to DHFS for review. This matter will be examined during inspection.

References: The documents referenced above are available electronically at NRC's web site, <http://www.nrc.gov>, under "Electronic Reading Room," then "Document Collections," then "Generic Communications" for IN's or "NUREG –Series Publications" for NUREGS.

Item 9.2 Radiation Monitoring Instruments

Rule: *HFS 157.25(1); HFS 157.31(3); HFS 157.13(2)*

Criteria: Licensees must possess, or have access to, radiation monitoring instruments which are necessary to protect health and minimize danger to life or property. Instruments used for quantitative radiation measurements must be calibrated at intervals not to exceed 12 months for the radiation measured.

Discussion: All licensees possessing self-shielded irradiators should have, or have access to, calibrated radiation detection instruments to determine radiation levels in areas adjacent to the irradiator. Usually, it is not necessary for a licensee to have a survey meter solely for use during irradiator operations, since it is not expected that a survey be performed each time a sample is irradiated. In these cases it is acceptable for the meter to be available on short notice in the event of an accident or malfunction that could reduce the shielding of the sealed source(s). Surveys may be required to verify source integrity and to ensure that dose rates in unrestricted areas and public and occupational doses are within regulatory limits.

As explained in an "Urgent Notice" with an enclosed Order, both dated July 3, 1984 (see **Appendix E**), an NRC licensee identified a malfunction that could have resulted in a radiation overexposure. The malfunction involved an interlock mechanism which would have failed to prevent a shielded door from being opened after the source had moved out of the shielded position. The Order, which remains in effect, modifies licenses which authorize J. L. Shepherd Mark I or Model 81-22 irradiators and requires licensee to provide either a calibrated and operable radiation survey meter or room monitor for use with either of these irradiators. Although not required for all licensees possessing moving-source irradiators, it would be prudent for these licensees to use either a calibrated survey meter or room monitor to ensure that the sources are in the shielded position whenever a sample is not undergoing irradiation.

DHFS requires that survey meter calibrations be performed by the instrument manufacturer or a person specifically authorized by DHFS, the NRC or an Agreement State, unless the applicant specifically requests this authorization. Applicants seeking authorization to perform survey meter calibrations must follow the survey instrument calibration program in **Appendix K** or submit alternative procedures for review.

Response from Applicant:

Item 9.2 Radiation Monitoring Instruments (Check one box)

- ☐ We will use instruments that meet the radiation monitoring instrument specifications published in Appendix K of WISREG "Guidance for Self Shielded Irradiators." Additionally, each survey meter will have been calibrated by the manufacturer or other person authorized by DHFS, the NRC or an Agreement State to perform survey meter calibrations no more than 12 months before the date the meter is used.
- OR
- ☐ We will use instruments that meet the radiation monitoring instrument specifications published in Appendix K of WISREG "Guidance for Self Shielded Irradiators." Additionally, we will implement the model survey meter calibration program published in Appendix K of WISREG "Guidance for Self Shielded Irradiators" and we ensure that each survey meter will have been calibrated no more than 12 months before the date the meter is used.
- OR
- ☐ We will have access to survey equipment and/or procedures for ensuring that interlocks function, as required, to return moving self shielded irradiator sources to the shielded position and/or determining source shielding integrity after an incident involving the self shielded irradiator.

Notes:

- Licenses authorizing J. L. Shepherd Mark I or Model 81-22 irradiators will be conditioned to require compliance with the terms of the Order in **Appendix E**. Applicants requesting these irradiators must ensure that their radiation detection instruments meet these requirements.

- Applicants who plan to perform non-routine maintenance that will affect safety-critical components (e.g., sealed source, radiation shielding, source movement control or mechanism, interlocks) will need to possess and use appropriate, calibrated radiation survey meters. Refer to the section on **Item 9.8 Maintenance, Appendix I, and Appendix K** for more information.
- Required calibration records must be retained for a minimum of 3 years.

Item 9.3: Material Receipt and Accountability

Rule: *HFS 157.13(9)(b) and (10); HFS 157.13(15); HFS 157.06(1); HFS 157.13(18); HFS 157.28(1)(a&b); HFS 157.32(1); HFS 157.15*

Criteria: Licensees must do the following:

- Maintain accountability for self-shielded irradiators by conducting physical inventories at intervals not to exceed 6 months (or as justified by the applicant) to account for all sealed sources.
- Maintain records of receipt, transfer, and disposal of self-shielded irradiators.

Discussion: While loss, theft, or misplacement of most self-shielded irradiators is unlikely because of their size and weight, accountability for licensed materials must be ensured; see **Figure 4**. Many licensees record use of self-shielded irradiators in a logbook. Licensees are also required to conduct leak tests of irradiator sealed source(s) at the frequency specified in the SSD Registration Certificate. Since both of these activities require that an individual approach the irradiator, records of use and leak tests may be used as part of an accountability program. For more information, see **Item 9.6 Operating and Emergency Procedures** and **Item 9.7 Leak Tests** in this guide. However, since some irradiators may not be in use or are used rarely, DHFS expects licensees to physically approach and account for all sealed sources at least every 6 months.

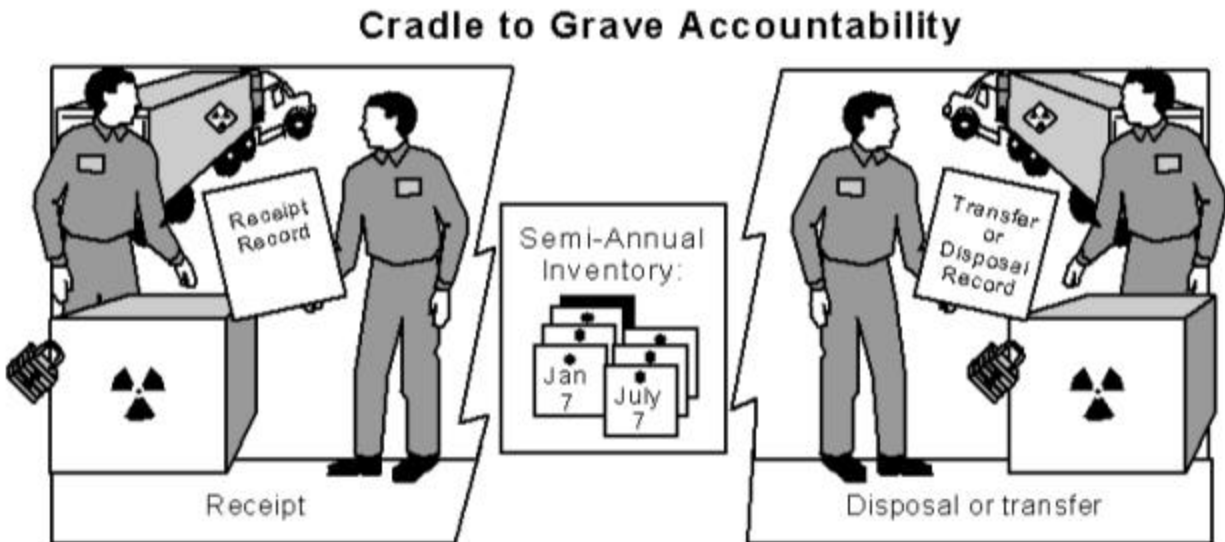


Figure 4. Material Receipt and Accountability. Licensees must maintain records of receipt, transfer, and disposal and conduct semiannual physical inventories.

Receipt, transfer, and disposal records must be maintained for the times specified in **Table 3**.

Typically, these records contain the following types of information:

- Radionuclide and activity (in units of becquerels or curies) of radioactive material in each sealed source
- Manufacturer's (or distributor's) name, model number, and serial number (if appropriate) of each device containing radioactive material
- Location of each sealed source and device
- For materials transferred or disposed of, the date of the transfer or disposal, name and license number of the recipient, description of the affected radioactive material (e.g., radionuclide, activity, manufacturer's (or distributor's) name and model number, serial number).

Information on locations where irradiators are used or stored are records important to decommissioning and required by **HFS 157.15**.

Table 3. Record Maintenance

| Type of Record | How Long Record Must be Maintained |
|--------------------------------|---|
| Receipt | For as long as the material is possessed until 3 years after transfer or disposal |
| Transfer | For 3 years after transfer |
| Disposal | Until DHFS terminates the license |
| Important to decommissioning * | Until the site is released for unrestricted use |

* See the **Item 7.1, Financial Assurance and Recordkeeping for decommissioning.**

Response from Applicant:

Item 9.3 Material Receipt And Accountability (Check one box)

- ☐ Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license.

Item 9.4: Occupational Dose

Rule: *HFS 157.25(2); HFS 157.22(1); HFS 157.22(7-8); HFS 157.31(7)*

Criteria: Applicants must do either of the following:

- Perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits as shown in **Figure 5**.

OR

- Provide dosimetry as follows:
 - Personnel dosimeters which are processed and evaluated by a National Voluntary Laboratory Accreditation Program (NVLAP) approved processor and are exchanged at a frequency recommended by the processor; or
 - Direct or indirect reading pocket ionization chambers that:

- Are assigned to a single individual whose accumulated dose is read, recorded, and the chamber recharged, as appropriate, before the chamber is assigned to another individual
- Have a range of 0 to at least 2 mSv (200 mrem)
- Are checked at intervals not to exceed one year for correct response to radiation
- Read within $\pm 20\%$ of the true radiation exposure
- Are used under a program that prescribes action to evaluate the individual's dose

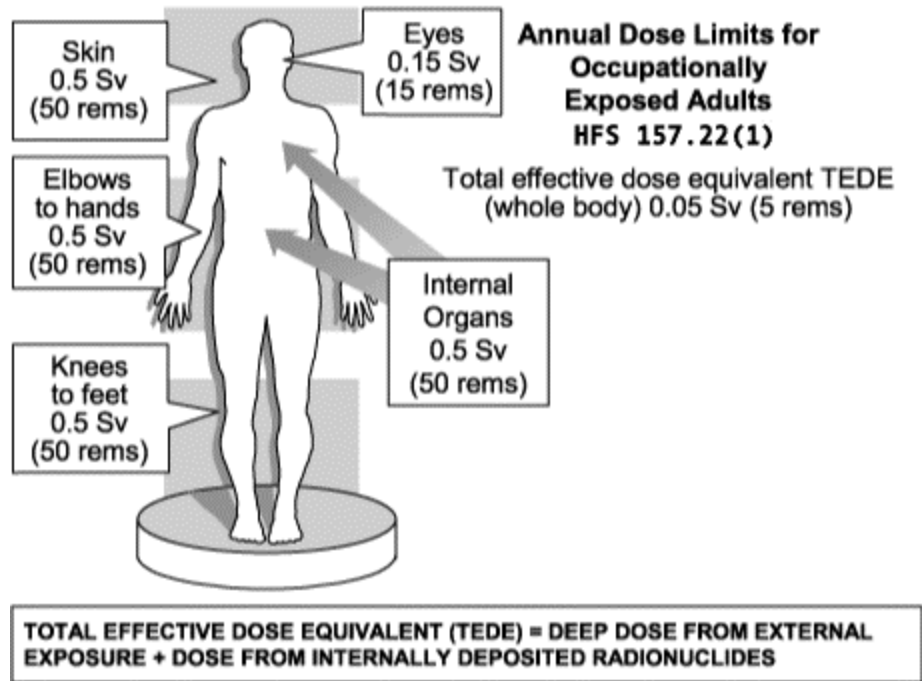


Figure 5. Annual Dose Limits for Occupationally Exposed Individuals.

Discussion: Under conditions of routine use and maintenance, the typical self-shielded irradiator user does not require a personnel monitoring device (dosimetry). However, individuals who perform non-routine maintenance do require personnel monitoring devices. **Appendix L** provides guidance on performing a prospective evaluation demonstrating that self-shielded irradiator users are not likely to exceed 10% of the applicable limits and thus, are not required to have personnel dosimetry.

When personnel monitoring is needed, most licensees use either film badges, TLDs or other approved similar devices that are supplied by a NVLAP-approved processor. The exchange frequency for film badges is usually monthly due to technical concerns about film fading. The

exchange frequency for TLDs is usually quarterly. Applicants should verify that the processor is NVLAP-approved. Consult the NVLAP-approved processor for its recommendations for exchange frequency and proper use.

Some licensees use self-reading dosimeters in lieu of processed dosimetry. This is acceptable if the criteria above are met. See ANSI N322, "Inspection and Test Specifications for Direct and Indirect Reading Quartz Fiber Pocket Dosimeters," for more information.

Response from Applicant:

Item 9.4 Occupational Dose (Check one box)

☐ We will maintain, for inspection by DHFS, documentation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits in s. HFS 157.22.

OR

☐ We will provide dosimetry processed and evaluated by a NVLAP-approved processor that is exchanged at a frequency recommended by the processor.

Note:

- Some licensees choose to provide personnel dosimetry to their workers for reasons other than compliance with DHFS requirements (e.g., to respond to worker requests).

References: National Institute of Standards and Technology (NIST) Publication 810, "National Voluntary Laboratory Accreditation Program Directory," is published annually and is available electronically at <http://ts.nist.gov/nvlap> . NIST Publication 810 can be purchased from GPO, whose URL is <http://www.gpo.gov>. ANSI N322 may be ordered electronically at <http://www.ansi.org> or by writing to ANSI, 1430 Broadway, New York, NY 10018.

Item 9.5: Public Dose

Rule: *HFS 157.23(1-2); HFS 157.03(278); HFS 157.28(1)(a&b); HFS 157.31(8)*

Criteria: Licensees must do the following:

- Ensure that licensed self-shielded irradiators will be used, transported, and stored in such a way that members of the public will not receive more than 1 mSv (100 mrem) in one

year, and the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any one hour, from licensed operations.

- Control and maintain constant surveillance over self-shielded irradiators that are not in storage and secure stored self-shielded irradiators from unauthorized access, removal, or use.

Discussion: Public dose is defined in **Chapter HFS 157 Subchapter I ‘General Provisions’** as the dose received by a member of the public from exposure to sources of radiation released by a licensee, or to any other source of radiation under the control of a licensee. Public dose excludes doses received from background radiation and from medical procedures. Whether the dose to an individual is an occupational dose or a public dose depends on the individual's assigned duties. It does not depend on the area (restricted, controlled, or unrestricted) the individual is in when the dose is received.

In the case of self-shielded irradiators, members of the public include persons who work or may be near locations where self-shielded irradiators are used or stored and employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where irradiators are used or stored.

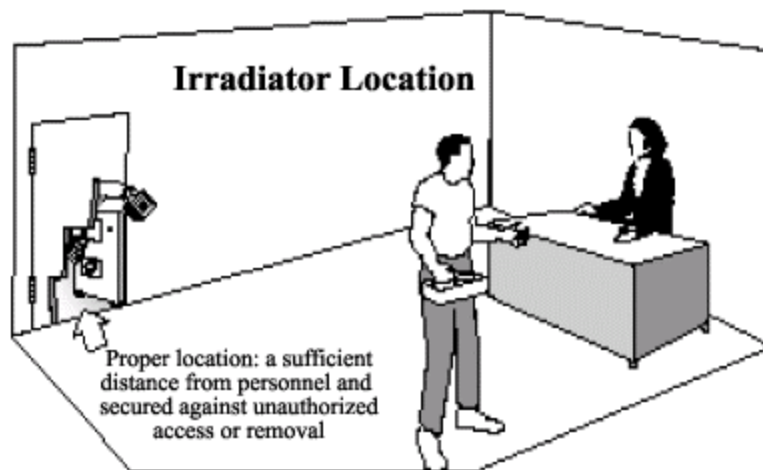


Figure 6. Proper Location of Irradiator. *Irradiators should be located away from occupied areas and secured to prevent unauthorized use or removal.*

Security procedures described in **Item 8 Facilities and Equipment** and **Item 9.6 Operating and Emergency Procedures** should be effective in limiting the exposure to the public during use or storage. See **Figure 6**. Public dose is controlled, in part, by ensuring that irradiators are secure

(e.g., located in a locked area) to prevent unauthorized access or use. As shown in **Figure 1**, most self-shielded irradiators are massive [i.e., hundreds of kilograms (pounds) and the size of file cabinets], not likely to be easily removed from their intended location, and may not need to be in a locked area to prevent loss, theft, or unauthorized relocation.

Smaller units, however, such as those used to calibrate TLDs, are more easily moved and should be located in a locked area or bolted in place. Irradiator use is usually restricted by controlling access to the keys needed to operate the irradiator and/or to keys to the locked irradiator area. Only authorized users should have access to these keys.

Public dose is also affected by the choice of storage and use locations and conditions. Since a self-shielded irradiator presents a radiation field, it must be located so that the radiation level in an unrestricted area (e.g., an office or the exterior surface of an outside wall) does not exceed 1 mSv (100 mrem) in a year or 0.02 mSv (2 mrem) in any one hour. Use the concepts of time, distance, and shielding when choosing storage and use locations. Decreasing the time spent near an irradiator, increasing the distance from the irradiator, and using shielding (i.e., brick, concrete, lead, or other solid walls) will reduce the radiation exposure.

Licensees can determine the radiation levels adjacent to the irradiator location either by calculations or a combination of direct measurements and calculations using some or all of the following: typical known radiation levels provided by the irradiator manufacturer (or distributor), the inverse square law to evaluate the effect of distance on radiation levels, occupancy factor to account for the actual presence of the member of the public, and limits on the use of self-shielded irradiator(s). See **Appendix M** for an example.

If, after making an initial evaluation, a licensee changes the conditions used for the evaluation (e.g., changes the location of irradiators, changes the type or frequency of irradiator use, adds self-shielded irradiators, changes the occupancy of adjacent areas), then the licensee must perform a new evaluation to ensure that the public dose limits are not exceeded and take corrective action, as needed.

During DHFS inspections, licensees must be able to provide documentation demonstrating, by measurement or calculation, that the TEDE to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public. See **Appendix M** for examples of methods to demonstrate compliance.

Response from Applicant:

Item 9.5 Public Dose

No response is required, in this license application, however the licensee's evaluation of public dose will be examined during an inspection.

Item 9.6: Operating and Emergency Procedures

Rule: *HFS 157.13(9-10); HFS 157.21; HFS 157.28(1)(a&b); HFS 157.32(2-3); HFS 157.13(17); HFS 157.88(1)*

Criteria: Before using an irradiator, licensees must do the following:

- Develop, implement, and maintain model-specific operating and emergency procedures containing the following elements:
 - An analysis of each type of material to be placed in the irradiator to ensure that it is compatible with the irradiator's design or to determine if any special safety procedures are needed
 - Instructions for using the self-shielded irradiator and performing routine maintenance, according to the manufacturer's (or distributor's) written recommendations and instructions
 - Instructions for maintaining security to prevent unauthorized use, access, or removal of self-shielded irradiators and the associated sealed sources
 - Steps to take to keep radiation exposures ALARA
 - Steps to maintain accountability
 - Steps to control access to malfunctioning or damaged irradiator
 - Steps to take, and whom to contact (e.g., RSO, local officials), when an irradiator malfunctions or has been damaged.

AND

- Provide copies of operating and emergency procedures to all users.

- Maintain a current copy of operating and emergency procedures at each irradiator's control panel (or, if this is not practicable, post a notice describing the procedures and stating where they may be examined).

Discussion: When used as designed, properly functioning self-shielded irradiators pose little radiation safety risk. However, improper maintenance, irradiating material incompatible with an irradiator's design, or operating an irradiator in an environment other than that recommended by the manufacturer (or distributor), could lead to damage or malfunction of an irradiator and elevated exposure rates in the irradiator's immediate vicinity. Operating and emergency procedures should be developed to minimize these risks, while keeping radiation exposures ALARA. These procedures must be model-specific to account for potentially significant differences in irradiator design and construction that lead to manufacturers (or distributors) providing different instructions and recommendations for operating and maintaining irradiators.

Sources contained in many self-shielded irradiators are designed to deliver significant doses in short periods of time. Although self-shielded irradiators are safe when used correctly, unauthorized access to the irradiator or the irradiator's sources by untrained individuals could lead to a life-threatening situation. Therefore, operating procedures will also need to address access control and accountability. Many licensees achieve access control by permitting only AUs or the RSO to have access to the keys for the irradiator and/or the irradiator area. Accountability of an operating irradiator may be ensured by using a logbook to record irradiator use, maintenance, service calls, and sealed source leak tests. Each activity requires an individual to interact in some way with the irradiator and thereby verify its presence. For sources contained in irradiators that are not actively used, licensees would need to find other methods to maintain accountability, such as conducting inventories.

Licensees must post current copies of the operating procedures applicable to licensed activities (e.g., at the irradiator control panel). If posting of a document is not practicable, the licensee may post a notice which describes the document and states where it may be examined.

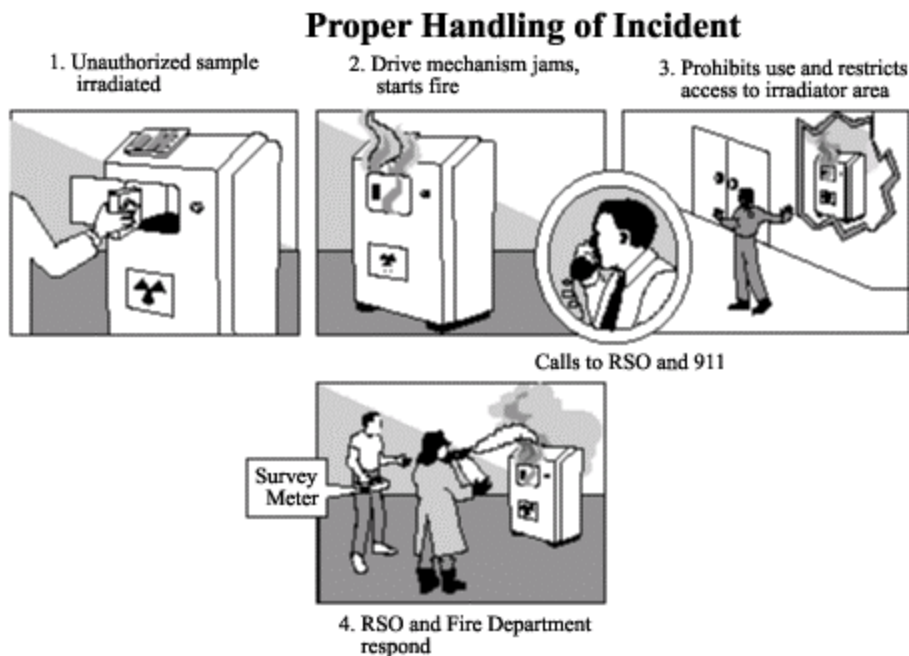


Figure 7. Proper Handling of Incident. Licensee personnel implement emergency procedures when a flammable sample catches fire.

Figure 7 illustrates proper response to a fire in an irradiator. Emergency procedures should be developed to address a spectrum of incidents (e.g., interlock failure, flood, earthquake).

Emergency response procedures should contain the following:

- Leave the irradiator room to reduce radiation exposure
- Control access (e.g., lock door)
- Contact the individual responsible for the irradiator program for further instructions and to initiate emergency response actions. Telephone numbers should be posted or easily accessible and should include the responsible individual, the irradiator manufacturer, distributor, or its representative, fire department, emergency response organizations, and DHFS

DHFS Emergency Response Telephone Numbers:
 (608) 267-4797 during office hours and
 (608) 258-0099 for 24-hr emergency response

- Survey areas outside the irradiator room to determine whether further restriction of the area is necessary to ensure that no one can enter the area if the radiation level exceeds 0.02 mSv (2 mrem) per hour

- As appropriate, require timely reporting to DHFS according to ***HFS 157.32(1-3) and HFS 157.13(17)***

DHFS must be notified when a self-shielded irradiator is lost, stolen, or other conditions occur. The RSO must be proactive in evaluating whether DHFS notification is required. Refer to **Appendix N** and the regulations (***HFS 157.32(1-3)*** and ***HFS 157.13(17)***) for a description of when and where notifications are required.

Appendix O provides information for applicants to consider when developing their procedures for self-shielded irradiators.

Response from Applicant:

Item 9.6 Operating And Emergency Procedures (Check one box)

- ☐ We will develop, implement, maintain and distribute operating procedures that will meet the Criteria in the section titled 'Operating and Emergency Procedures' in WISREG "Guidance for Self Shielded Irradiators." (Procedures are attached)
- OR
- ☐ We will submit alternative procedures. (Procedures are attached)

Note:

- Licenses authorizing J. L. Shepherd Mark I or Model 81-22 irradiators will be conditioned to require compliance with the terms of the Order in **Appendix E**. Applicants requesting these irradiators must ensure that their operating and emergency procedures address these requirements.
- Before using a new model irradiator, licensees need to revise operating and emergency procedures to include procedures specific to the new irradiator.

Item 9.7: Leak Tests

Rule: ***HFS 157.06(3); HFS 157.25(1); HFS 157.31(3)***

Criteria: DHFS requires testing to determine whether there is any radioactive leakage from the source in the self-shielded irradiator. Records of test results must be maintained.

Discussion: Licensees will perform leak tests at six-month intervals or as approved in the SSD Registration Certificate. The measurement of the leak-test sample is a quantitative analysis

requiring that instrumentation used to analyze the sample be capable of detecting 185 Bq (0.005 microcurie) of radioactivity.

Manufacturers, consultants, and other organizations may be authorized by DHFS, the NRC or an Agreement State to either perform the entire leak test sequence for other licensees or provide leak test kits to licensees. In the latter case, the licensee is expected to take the leak test sample according to the self-shielded irradiator manufacturer's (or distributor's) and the kit supplier's instructions and return it to the kit supplier for evaluation and reporting results. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking. Licensees may also be authorized to conduct the entire leak test sequence themselves.

Response from Applicant:

Item 9.7 Leak Tests (Check one)

- ☐ Leak tests will be performed by an organization authorized by DHFS, the NRC or an Agreement State to provide leak testing services to other licensees; or by using a leak test kit supplied by an organization licensed by DHFS, the NRC or an Agreement State to provide leak test kits to other licensees according to kit supplier's instructions.

List Name and License number of organization authorized to perform or analyze leak test (Specify whether DHFS, NRC, or other Agreement State)

Organization Name _____ License Number _____

Note: An alternate organization may be used to perform or analyze leak test, without amending the license, provided the organization is specifically authorized by DHFS, NRC, or an Agreement State.

OR

- ☐ We will perform leak testing and sample analysis and will follow the model procedures in Appendix P of WISREG "Guidance for Self Shielded Irradiators." (Procedures are attached)

OR

- ☐ We will submit alternative procedures. (Procedures are attached)

Note:

- Alternative responses will be reviewed using the criteria listed above.
- If a self-shielded irradiator is added to an existing license, that license might already authorize the licensee to perform the entire leak test sequence. In this case, the licensee may perform the leak testing on the irradiator according to the procedures previously approved on its license.

References: See Section 8.10.8 and Appendix O of NRC NUREG 1556 Vol. 18 "Program Specific Guidance about Service Provider Licenses," and is available electronically at NRC's

web site, <http://www.nrc.gov>, under “Electronic Reading Room,” then “All Collections,” the “NUREG-Series Publications.”

Item 9.8: Maintenance

Rule: *HFS 157.21; HFS 157.13(9-10)*

Criteria: Licensees must routinely maintain self-shielded irradiators according to the manufacturer's (or distributor's) written recommendations and instructions; see **Figure 8**. For self-shielded irradiators, radiation safety procedures for routine maintenance must consider ALARA and ensure that the irradiator functions as designed and source integrity is not compromised.

In this guide, "non-routine maintenance" means any repair, removal, replacement, or alteration involving: electrical and mechanical systems that control source or shielding movement, the irradiator's shielding or sealed source, safety interlocks, any component that may affect safe operation of the irradiator, or any other activities during which personnel could receive radiation doses exceeding DHFS limits.

Non-routine maintenance must be performed by the self-shielded irradiator manufacturer (or distributor) or a person specifically authorized by DHFS, the NRC or an Agreement State; see **Figure 9**. Requests for specific authorization to perform non-routine maintenance (see **Appendix I**) must demonstrate that personnel performing the work do the following:

- Have adequate training and experience
- Use equipment and procedures that ensure compliance with regulatory requirements, and consider ALARA
- Ensure that the self-shielded irradiator functions as designed and that source integrity is not compromised.

Discussion: NRC IN 96-35, "Failure of Safety Systems on Self-Shielded Irradiators because of Inadequate Maintenance and Training," dated June 11, 1996, emphasizes the importance of proper maintenance and describes two incidents in which safety interlocks on self-shielded irradiators failed to prevent inadvertent exposure. Generally, before any maintenance or repair work is done, licensees need to determine (and assure themselves of the adequacy of) the following:

- The tasks to be performed
- The protocol or procedures to be followed
- The radiation safety procedures including possible need for compensatory measures (e.g., steps taken to compensate for lack of or reduced shielding)
- ALARA considerations
- Training and experience of personnel performing the work
- The qualification of parts, components, other materials to be used in the irradiator
- The tests (to be performed before the irradiator is returned to routine use) to ensure that it functions as designed.

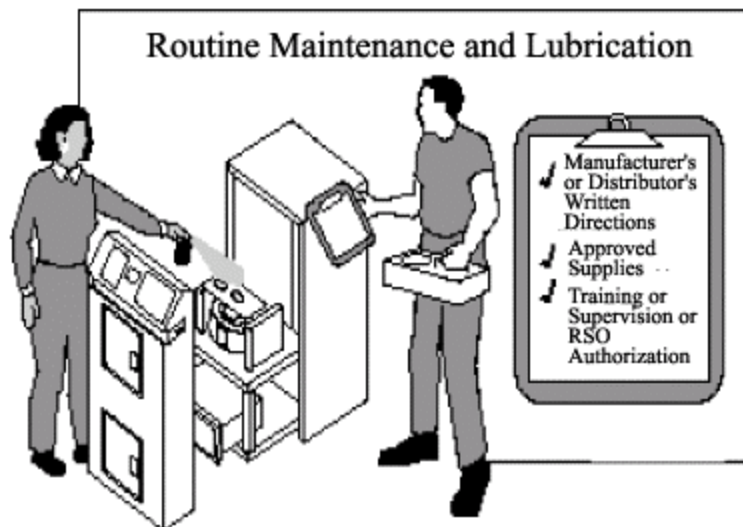


Figure 8. Routine Maintenance and Lubrication. *To ensure proper operation of the unit, self-shielded irradiator licensees need to perform routine maintenance according to the manufacturer's (or distributor's) written instructions and recommendations.*

DHFS permits self-shielded irradiator licensees to perform routine maintenance of the irradiator provided they follow the self-shielded irradiator manufacturer's (or distributor's) written recommendations and instructions. Although manufacturers (or distributors) may use different terms, "routine maintenance" includes, but is not limited to, cleaning, lubrication, changing batteries, relays or fuses. Routine maintenance does *not* include any activities that involve the source, source drive mechanism, or removing the shielding or source and any other activities during which personnel could receive radiation doses exceeding DHFS limits.

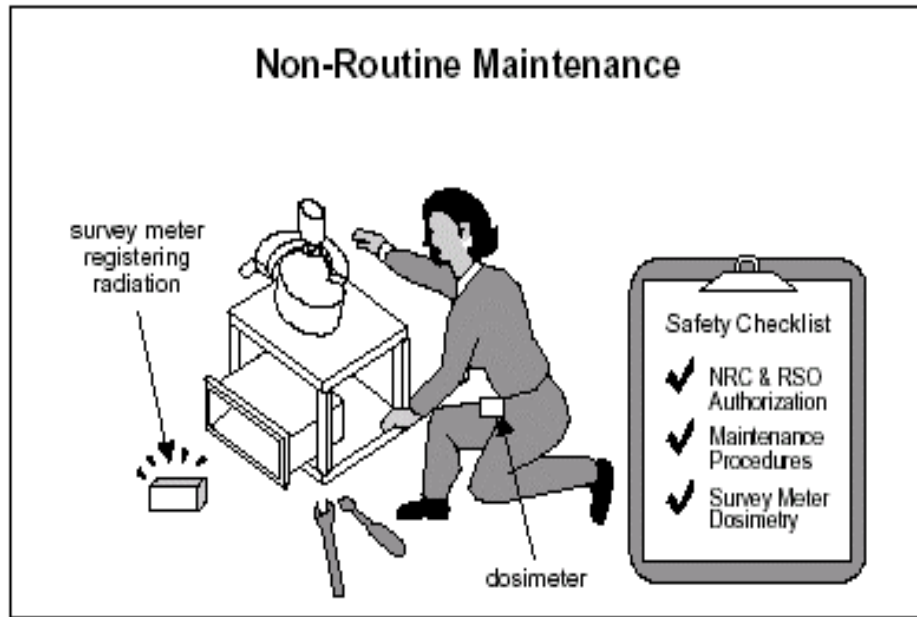


Figure 9. Non-Routine Maintenance. *For non-routine maintenance, most licensees rely on the manufacturer, distributor, or other service companies.*

The DHFS license will require that non-routine maintenance (as defined above) be performed only by the manufacturer (or distributor) or other persons specifically licensed by DHFS, the NRC or an Agreement State to perform such services. Most licensees do not perform non-routine maintenance because they must have specialized equipment and technical expertise to perform these activities. Applicants seeking authorization to perform non-routine maintenance must submit specific procedures for review. See **Appendix I** for more information.

Response from Applicant:

Item 9.8 Maintenance (Check one box for Routine Cleaning and Lubrication and one for Non-Routine Maintenance)

ROUTINE CLEANING AND LUBRICATION:

- ☐ We will implement and maintain procedures for routine maintenance of our self shielded irradiators according to each manufacturer's (or distributor's) written recommendations and instructions.

OR

- ☐ Alternative procedures are attached.

NON-ROUTINE MAINTENANCE:

- ☐ We will have the self shielded irradiator manufacturer (or distributor) or other person authorized by DHFS, the NRC or an Agreement State perform the non-routine maintenance.

OR

- ☐ We will provide procedures that address the information listed in Appendix I of WISREG "Guidance for Self Shielded Irradiators" supporting a request for authorization to perform this work. (Procedures attached)

Note:

- Information requested in **Appendix I** will be reviewed on a case-by-case basis; if approved, the license will contain a condition authorizing the licensee to perform non-routine maintenance.

References: INs are available electronically at NRC's web site, <http://www.nrc.gov>, under "Electronic Reading Room," then "Document Collections," then "Generic Communications" for IN's.

Item 9.9: Transportation

Rule: *HFS 157.92(3); HFS 157.93(4-6); 49 CFR 171; 49 CFR 172; 49 CFR 173; 49 CFR 174; 49 CFR 175; 49 CFR 176; 49 CFR 177; 49 CFR 178, HFS 157.21; HFS 157.13(15); HFS 157.06(1); HFS 157.13(18)*

Criteria: Applicants must develop, implement, and maintain safety programs for transport of radioactive material to ensure compliance with DHFS and DOT regulations.

Discussion: Most irradiator licensees chose to transfer possession of radioactive materials to an irradiator manufacturer, distributor or service licensee licensed with DHFS, the NRC or Agreement State who then acts as the shipper. The manufacturer, distributor or service licensee is subject to the provisions of *HFS 157.93(4)* or *HFS 157.93(6)*, as appropriate. They are responsible for proper packaging of the radioactive materials and compliance with DHFS and

DOT regulations. Licensees who do this must ensure that the manufacturer, distributor or service licensee:

- Is authorized to possess the irradiator at temporary job sites (e.g., at the irradiator location)
- Actually takes possession of the irradiator under its license
- Uses an approved Type B package
- Is registered with NRC as a user of the Type B package
- Has a DHFS, NRC or an Agreement State approved QA plan.

For each shipment, it must be clear who possesses the licensed material and is responsible for proper packaging of the radioactive materials and compliance with NRC and DOT regulations.

The general license in *HFS 157.93(4)* provides the authorization used by most licensees to transport, or offer for transport, packages of radioactive material and specifies certain conditions. Most self-shielded irradiators contain quantities of radioactive material that require using a Type B package. Before offering a Type B package for shipment, the licensee needs to be registered as a user of the package and have an DHFS-approved quality assurance (QA) plan, two of the requirements under the *HFS 157.93(4)* general license. For information about QA plans, see Rev. 1 of NRC RG 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," dated June 1986. For further information about registering as a user of a package, contact NRC's Spent Fuel Project Office (SFPO) by calling NRC's toll-free number 800-368-5642 and asking for extension 415-8500. For information about associated fees, contact NRC's OCFO by calling NRC's toll-free number 800-368-5642 and asking for extension 415-7554.

During an inspection, DHFS uses the provisions of *HFS 157.92(3)* to examine and enforce various DOT requirements applicable to irradiator licensees. **Part 1 of Appendix Q** lists major DOT regulations and **Part 2** contains a sample bill of lading.

Before the adoption of the requirements of 10 CFR Part 71 in 1966, self-shielded irradiators could be transported without being evaluated under the hypothetical accident conditions that are now incorporated in **10 CFR 71**. Because pre-1966 irradiators are not certified shipping packages, transporting them may require transferring the sealed source from the irradiator to a certified Type B package or using a certified package for the irradiator containing the sealed sources. Only if these options are not viable will DHFS consider a licensee's request for an exemption for a one-time shipment according to **HFS 157.04(1)**. Exemption requests should contain the information described in Part 3 of **Appendix Q**. In addition to a DHFS exemption, the licensee may also need a DOT exemption; contact DOT's Office of Hazardous Materials Technology at 202-366-4545 for additional information.

Response from Applicant:

Item 9.9 Transportation

- ☐ We choose to transfer possession of radioactive material to an irradiator manufacturer, distributor or service licensee with a DHFS, NRC or Agreement State license who then acts as the shipper.
- OR
- ☐ Before offering a Type B package for shipment we will be registered with the NRC as user of the package and obtain DHFS approval of our QA program.

References: "A Review of Department of Transportation Regulations for Transportation of Radioactive Materials (1998 revision)" can be obtained by calling DOT's Office of Hazardous Material Initiatives and Training at (202) 366-4425 or at the following website <http://hazmat.dot.gov/pubtrain/ramreview.pdf> NRC Regulatory Guides are available electronically at NRC's web site, <http://www.nrc.gov>, under "Electronic Reading Room," then "Document Collections," then "Regulatory Guides."

Item 9.10: Minimization of Contamination

Rule: *HFS 157.13(2)(b)*

Criteria: Applicants for new licenses must describe how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

Discussion: All applicants for new licenses need to consider the importance of designing and operating their facilities to minimize the amount of radioactive contamination generated at the site during its operating lifetime and to minimize the generation of radioactive waste during

decontamination. Irradiator applicants usually do not need to address these issues as a separate item since they are included in responses to other items of the application.

Sealed sources and devices that are approved by DHFS, the NRC or an Agreement State and located and used according to their SSD Registration Certificates usually pose little risk of contamination. Leak tests performed as specified in the SSD Registration Certificate should identify defective sources. Leaking sources must be immediately withdrawn from use and decontaminated, repaired, or disposed of according to DHFS requirements. These steps minimize the spread of contamination and reduce radioactive waste associated with decontamination efforts. Other efforts to minimize radioactive waste do not apply to programs using only sealed sources and devices that have not leaked.

Note: DHFS will consider that the above criteria has been met if the applicant's responses meet the criteria in the following items: **Item 7 'Radioactive Material'; Item 9.6 'Operating and Emergency Procedures'; Item 9.7 'Leak Test'; Item 10 'Self-Shielded Irradiator Disposal and Transfer.'**

Item 10: Disposal, Transfer and License Termination

Item 10.1: Disposal and Transfer

Rule: *HFS 157.30(1); HFS 157.13(15); HFS 157.06(1); HFS 157.13(18)*

Criteria: Licensed materials must be disposed of according to DHFS requirements by transfer to an authorized recipient. Appropriate records must be maintained.

Discussion: When disposing of self-shielded irradiators, licensees must transfer them to an authorized recipient. Authorized recipients are the original manufacturer (or distributor) of the irradiator, a commercial firm licensed by DHFS, the NRC or an Agreement State to accept radioactive waste from other persons, or another specific licensee authorized to possess the licensed material (i.e., its license specifically authorizes the same radionuclide, form, and use).

Before transferring radioactive material, a licensee must verify that the recipient is properly authorized to receive it using one of the methods described in *HFS 157.13(15)*. In addition, all

packages containing radioactive sources must be prepared and shipped according to DHFS and DOT regulations. Records of the transfer must be maintained as required by *HFS 157.13(18)*.

Licensees should promptly dispose of unused irradiators to minimize potential problems of access by unauthorized individuals, use for inappropriate purposes, or improper disposal.

Response from Applicant:

Item 10.1 Disposal And Transfer (Check Box)

- ☐ We will return the source to the manufacturer for disposal or transfer the device to a specific licensee authorized to receive radioactive material.

Note: Because of the difficulties and costs associated with disposal of sealed sources, applicants should preplan the disposal. Applicants may want to consider contractual arrangements with the source supplier as part of a purchase agreement.

Item 10.2: Termination of Activities

Rule: *HFS 157.33(2); HFS 157.13(9-10); HFS 157.15; HFS 157.13(11); HFS 157.06(1); HFS 157.13(18)*

Criteria: The licensee must do the following:

- Notify DHFS, in writing, within 30 days of the decision to permanently discontinue all activities involving materials authorized under the license.
- Notify DHFS, in writing, within 60 days of:
 - The expiration of its license
 - A decision to permanently cease licensed activities at the entire site (regardless of contamination levels)
 - A decision to permanently cease licensed activities in any separate building or outdoor area, if they contain residual radioactivity making them unsuitable for release according to DHFS requirements
 - No principal activities having been conducted at the entire site under the license for a period of 24 months

- No principal activities having been conducted for a period of 24 months in any separate building or outdoor area, if they contain residual radioactivity making them unsuitable for release according to DHFS requirements.
- Submit a decommissioning plan, if required by **HFS 157.13(11)**.
- Conduct decommissioning, as required by **HFS 157.13(11)**.
- Submit, to DHFS, a completed DPH Form 45008 '*Certificate of Disposition of Materials*' (or equivalent information) and a demonstration that the premises are suitable for release for unrestricted use (e.g., results of final survey).
- Before a license is terminated, send the records important to decommissioning to DHFS. If licensed activities are transferred or assigned in accordance with **HFS 157.13(9-10)**, transfer records important to decommissioning to the new licensee.

Discussion: As noted in several instances discussed in "**Criteria**," before a licensee can decide whether it must notify DHFS, the licensee must determine whether residual radioactivity is present and if so, whether the levels make the building or outdoor area unsuitable for release according to DHFS requirements. A licensee's determination that a facility is not contaminated is subject to verification by DHFS inspection.

For guidance on the disposition of licensed material, see the **Item 10. Self-Shielded Irradiator Disposal or Transfer**. For guidance on decommissioning records, see **Item 7.1 Financial Assurance and Record Keeping for Decommissioning**.

Response from Applicant:

Item 10.2 Termination Of Activities (Check box)

- ☐ We will notify DHFS, in writing, within 30 days of the decision to permanently cease radioactive material use per s. HFS 157.13(10)(d)

Reference: See **Appendix B** for DPH Form 45008, "*Certificate of Disposition of Materials*."

Item 11: LICENSE FEES

On DPH Form 45014 '*Application for Radioactive Material Authorizing the Use of Self Shielded Irradiator Devices*' enter the fee category and the amount. Enclose fee with the application.

Response from Applicant:

Item 11 License Fees (Refer to Wisconsin Administrative Code HFS 157.10)

Category:

License fee enclosed:

☐ Yes☐ No

Amount Enclosed _____

Item 12: CERTIFICATION

Individuals acting in a private capacity are required to sign and date DPH Form 45014 *'Application for Radioactive Material Authorizing the Use of Self Shielded Irradiator Devices'*. Otherwise, senior representatives of the corporation or legal entity filing the application should sign and date DPH Form 45014 *'Application for Radioactive Material Authorizing the Use of Self Shielded Irradiator Devices'*. **Representatives signing an application must be authorized to make binding commitments and sign official documents on behalf of the applicant.** As discussed previously in "Management Responsibility," signing the application acknowledges management's commitment and responsibilities for the radiation protection program. The department **will return all unsigned applications for proper signature.**

Note:

- It is a violation of **HFS 157.05(2)**, to make a willful false statement or representation on applications or correspondence.
- When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

Response from Applicant:**Item 12**

I hereby certify that this application was prepared in conformance with Wisconsin Administrative Code HFS 157 "Radiation Protection" and that all information contained herein, including any supplements attached hereto, is true and correct to the best of my knowledge and belief

SIGNATURE - Applicant Or Authorized Individual

Date signed:

Print Name and Title of above signatory

APPENDIX A

DPH 45014

***APPLICATION FOR RADIOACTIVE
MATERIAL LICENSE AUTHORIZING THE
USE OF SELF SHIELED IRRADIATOR***

To access this form please go to:

<http://dhfs.wisconsin.gov/forms/DPH/dph45014.pdf>

APPENDIX B

DPH 45007

***CERTIFICATE OF DISPOSITION OF
MATERIALS***

To access this form please go to:

<http://dhfs.wisconsin.gov/forms/DPH/dph45007.pdf>

APPENDIX C

RESERVED

Appendix D

Information Needed for Transfer of Control Application

Information Needed for Transfer of Control

Licensees must provide full information and obtain DHFS's *prior written consent* before transferring control of the license; some licensees refer to this as "transferring the license." Provide the following information concerning changes of control by the applicant (transferor and/or transferee, as appropriate). If any items are not applicable, so state.

1. The new name of the licensed organization. If there is no change, the licensee should so state.
2. The new licensee contact and telephone number(s) to facilitate communications.
3. Any changes in personnel having control over licensed activities (e.g., officers of a corporation) and any changes in personnel named in the license such as radiation safety officer, authorized users, or any other persons identified in previous license applications as responsible for radiation safety or use of licensed material. The licensee should include information concerning the qualifications, training, and responsibilities of new individuals.
4. An indication of whether the transferor will remain in non-licensed business without the license.
5. A complete, clear description of the transaction, including any transfer of stocks or assets, mergers, etc., so that legal counsel is able, when necessary, to differentiate between name changes and transferring control.
6. A complete description of any planned changes in organization, location, facility, equipment, or procedures (i.e., changes in operating or emergency procedures).
7. A detailed description of any changes in the use, possession, location, or storage of the licensed materials.
8. Any changes in organization, location, facilities, equipment, procedures, or personnel that would require a license amendment even without transferring control.

9. An indication of whether all surveillance items and records (e.g., calibrations, leak tests, surveys, inventories, and accountability requirements) will be current at the time of transfer.
Provide a description of the status of all surveillance requirements and records.
10. Confirmation that all records concerning the safe and effective decommissioning of the facility, pursuant to *HFS 157.15*; public dose; and waste disposal by release to sewers, incineration, radioactive material spills, and on-site burials, have been transferred to the new licensee, if licensed activities will continue at the same location, or to DHFS for license terminations.
11. A description of the status of the facility. Specifically, the presence or absence of contamination should be documented. If contamination is present, will decontamination occur before transfer? If not, does the successor company agree to assume full liability for the decontamination of the facility or site?
12. A description of any decontamination plans, including financial assurance arrangements of the transferee, as specified in *HFS 157.15*. Include information about how the transferee and transferor propose to divide the transferor's assets, and responsibility for any cleanup needed at the time of transfer.
13. Confirmation that the transferee agrees to abide by all commitments and representations previously made to DHFS by the transferor. These include, but are not limited to: maintaining decommissioning records required by *HFS 157.15*; implementing decontamination activities and decommissioning of the site; and completing corrective actions for open inspection items and enforcement actions.

With regard to contamination of facilities and equipment, the transferee should confirm, in writing, that it accepts full liability for the site, and should provide evidence of adequate resources to fund decommissioning; or the transferor should provide a commitment to decontaminate the facility before transferring control.

With regard to open inspection items, etc., the transferee should confirm, in writing, that it accepts full responsibility for open inspection items and/or any resulting enforcement actions; or the transferee proposes alternative measures for meeting the requirements; or the transferor provides a commitment to close out all such actions with DHFS before license transfer.

14. Documentation that the transferor and transferee agree to transferring control of the licensed material and activity, and the conditions of transfer; and the transferee is made aware of all open inspection items and its responsibility for possible resulting enforcement actions.
15. A commitment by the transferee to abide by all constraints, conditions, requirements, representations, and commitments identified in the existing license. If not, the transferee must provide a description of its program, to ensure compliance with the license and regulations.

Appendix E

J. L. Shepherd Order

J. L. Shepherd Order

**JULY 3, 1984
UNITED STATES
NUCLEAR REGULATORY COMMISSION
URGENT NOTICE**

TO ALL LICENSEES WHO POSSESS J. L. SHEPHERD IRRADIATORS

An NRC licensee recently identified a malfunction in the lock mechanism of its J. L. Shepherd self-shielded irradiator which could have resulted in a radiation overexposure. Although no overexposure appears to have occurred, the potential hazard warrants immediate preventive action. Therefore, we have prepared the enclosed Order which requires the use of radiation survey equipment when the irradiators are being used.

If you possess a J. L. Shepherd Mark I or Model 81-22 self-shielded irradiator, do not use it unless you provide appropriate radiation monitoring as specified in the Order. If you do not currently possess the appropriate equipment, you must obtain it before you resume use of your irradiator. Also, you should report any problems to your nearest NRC regional office immediately. Do not attempt to repair an irradiator, or allow anyone else to attempt repairs, unless specific authorization for repair of the irradiator which you possess is provided in an NRC license.

We suggest that you review who has access to your irradiator, and establish strict controls to assure that no untrained personnel have access. Trained persons who continue to use the irradiator should conduct careful radiation surveys as specified in the Order. Irradiator doors should be opened slowly, to minimize any accidental exposure and to avoid "blinking out" of instruments due to high exposure rates. Any unusual meter reading should be taken as evidence of a problem.

We are including in this mailing certain licensees about which we are uncertain whether they possess J. L. Shepherd irradiators. If you do not possess a J. L. Shepherd irradiator, please disregard this notice.

Because this Order is effective immediately, it is important that you notify your radiation safety personnel immediately, and retain this Order with your license records. Questions and comments may be directed to your nearest NRC regional office.

Sincerely,
Richard E. Cunningham, Director
Division of Fuel Cycle and Material Safety
Enclosure: Order Modifying License

**UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D. C. 20555**

ORDER MODIFYING CERTAIN LICENSES (EFFECTIVE IMMEDIATELY)

I

Recently, the Nuclear Regulatory Commission (NRC) staff was notified by a licensee of the failure of a locking mechanism on a self-shielded irradiator which could have resulted in a radiation overexposure. ("Self-shielded" irradiators are designed so that the radioactive source remains in a shielded position at all times, both during storage and during irradiations. Therefore, the irradiators need not be placed in a shielded room.)

The irradiator is a J. L. Shepherd Mark I, containing about 6,000 curies of cesium 137. The unit is operated as follows: (1) With the source in its shielded storage position, the shielded door is opened, (2) materials to be irradiated are placed inside the irradiator chamber, (3) the shielded door is closed, (4) the radioactive source is raised into the irradiation chamber, (5) after irradiation is complete, the source is lowered, and (6) the door is opened for removal of irradiated materials.

The shielded door is interlocked so that it should not open when the radioactive source is in the irradiation chamber. However, in the case reported to NRC, the lock mechanism failed. In such a situation, an operator who opens the shielded door with the source raised could be subjected to substantial radiation exposure. The J. L. Shepherd Model 81-22 irradiator employs an interlock similar to the Mark I.

The NRC staff has examined the irradiator in question and confirmed the defect. Furthermore, a New York City inspector checking a J. L. Shepherd Mark I irradiator in New York reported a malfunctioning interlock system. NRC and the Agreement States are studying the problem further to assess its generic implications.

Based on the foregoing, I have concluded that the possibility of failure of locking mechanisms and/or mechanical timers on J. L. Shepherd Mark I and Model 81-22 irradiators represents a potential radiation hazard warranting immediate preventive action pending further investigation. I have determined, therefore, that the public health, safety, and interest require that the restrictions on the use of such irradiators as prescribed in Section II of this Order should be made immediately effective.

II

Accordingly, pursuant to Sections 81, 116 I, 162 o, and 182 of the Atomic Energy Act of 1954, as amended, and 10 CFR Parts 2 and 30 of the Commission's regulations, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT:

Each license that authorizes possession of byproduct material in a J. L. Shepherd Mark I or Model 81-22 self-shielded irradiator is hereby amended to add the following conditions:

1. The J. L. Shepherd irradiator shall not be used unless the licensee provides a calibrated and operable radiation survey meter or room monitor for use with the irradiator.
2. The irradiator door shall not be opened until the operator has checked visual indicators to verify that the source has returned to its safe storage position.
3. Each room monitor (a) shall be operable at all times when the irradiator is in use, (b) shall activate a visible and audible alarm when radiation levels exceed 2 millirems per hour, (c) shall be located to detect any radiation escaping from the irradiator door, and (d) shall be located so that it is visible to the irradiator user when he is next to the irradiator.
4. If a room monitor is not installed, a survey meter shall be used (a) to determine the radiation level at the irradiator door when the door is closed, and (b) to check for any increase in radiation levels each time the irradiator door is opened. In conducting such checks, operators shall position themselves so as to minimize exposure to any radiation escaping from the open door.
5. If abnormal radiation levels or any malfunction of the irradiator are detected at any time, the licensee shall stop use of the irradiator and immediately notify the appropriate NRC regional office by telephone.
6. The licensee shall not attempt repair or authorize others to attempt repair of the irradiator except as specifically authorized in a license issued by NRC.

III

Any affected licensee may request a hearing on this Order. A request for a hearing shall be submitted within twenty (20) days of the date of this Order to Mr. R. E. Cunningham, Director, Division of Fuel Cycle and Material Safety, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555, with a copy to the Executive Legal Director, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555. ANY REQUEST FOR A HEARING SHALL NOT STAY THE IMMEDIATE EFFECTIVENESS OF THIS ORDER.

IV

If a hearing is requested, the Commission will issue an Order designating the time and place of any such hearing. If a hearing is held the issue to be considered at such a hearing will be: Whether, on the basis of the matters set forth in Section 1 and II of this Order, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

Richard E. Cunningham, Director
Division of Fuel Cycle and Material Safety
Office of Nuclear Material Safety and Safeguards

Dated at Bethesda, Maryland this 3rd day of July, 1984

Appendix F

Guidance on Financial Assurance

Guidance on Financial Assurance

Determining Need for Financial Assurance

If the only radioactive materials possessed are sealed sources in self-shielded irradiators, use **Table 4** to determine if financial assurance is required.

Table 4. Worksheet for Determining Need for Financial Assurance for Self-Shielded Irradiators

| Step No. | Description | Cobalt-60 | Cesium-137 | Strontium-90 |
|----------|--|-----------|------------|--------------|
| 1 | Activity possessed, in Curies* | | | |
| 2 | Activity requiring financial assurance, in Curies | 10,000 | 100,000 | 1,000 |
| 3 | Divide data in Step 1 by data in Step 2 = FRACTION | | | |
| 4 | Add the fractions determined in Step 3 | | | |

*For ease of use by most irradiator licensees, this table uses only conventional units. The conversion to SI units is: 1 Ci = 37 GBq.

If the sum of the fractions is greater than or equal to 1, the applicant will need to submit certification of financial assurance or a decommissioning funding plan (*HFS 157.15*). NRC RG 3.66,(4) "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72," dated June 1990, provides sample documents for financial mechanisms. The recommended wording for a Statement of Intent for government licensees is shown below.

Note: NRC RG 3.66 is available electronically at NRC's web site, <http://www.nrc.gov>, under "Electronic Reading Room," then "Document Collections," then "Regulatory Guides."

Suggested Wording for a Statement of Intent for a Government Licensee

[DATE]

**TO: Department of Health and Family Services
Radiation Protection Section
P.O. Box 2659
Madison, WI 53701-2659**

STATEMENT OF INTENT

As *[Title]* of *[Licensee Name]* I exercise express authority and responsibility to approve funding for decommissioning activities associated with operations authorized by State of Wisconsin DHFS Material License No. *[License Number]*. This authority is established by *[Name of Document(s) Governing Control of Funds]*. Within this authority, I intend to have funds made available when necessary in an amount up to *[Dollar Amount]* to decommission *[Description of Facilities]*. I intend to request and obtain these funds sufficiently in advance of decommissioning to prevent delay of required activities.

A copy of *[Name of Documents]* is attached as evidence that I am authorized to represent *[Licensee Name]* in this transaction.

[SIGNATURE]

[NAME]

[TITLE]

Attachment: As stated

Appendix G

Training Program for Authorized Users and Radiation Safety Officers

Training Program for Authorized Users and Radiation Safety Officers

Course Content

Training may be in the form of lecture, videotape, hands-on, or self-study, and emphasizes practical subjects important to the safe use of the self-shielded irradiator:

- Radiation Safety
 - Radiation vs. contamination
 - Internal vs. external exposure
 - Biological effects of radiation
 - Types and relative hazards of radioactive material possessed
 - ALARA concept
 - Use of time, distance, and shielding to minimize exposure
 - Use of radiation detection instruments.

- Regulatory Requirements
 - Locations of use and storage of radioactive materials
 - Material control and accountability
 - Annual audit of radiation safety program
 - License conditions, amendments, renewals
 - Transfer and disposal
 - Recordkeeping
 - Handling incidents
 - Licensing and inspection by regulatory agency
 - Need for complete and accurate information
 - Employee protection
 - Deliberate misconduct.

- Practical Explanation of the Theory and Operation for Each Irradiator Possessed by the Licensee
 - Routine vs. non-routine maintenance
 - Operating and emergency procedures
 - Prior events involving self-shielded irradiators.

Instructor's Qualifications

The individual preparing and conducting training is qualified as RSO or AU on a self-shielded irradiator license before giving training.

Training Assessment

Management will ensure that potential RSOs and authorized users are qualified to work independently with each type of the licensee's irradiators. This may be demonstrated by written or oral examination or by observation.

Appendix H

Typical Duties and Responsibilities of the Radiation Safety Officer

Typical Duties and Responsibilities of the Radiation Safety Officer

The RSO's duties and responsibilities include ensuring radiological safety and compliance with DHFS and DOT regulations and the conditions of the license; see **Figure 3**. Typically, these duties and responsibilities include ensuring the following:

- Activities involving licensed material that the RSO considers unsafe are stopped
- Radiation exposures are ALARA
- Posting of required documents, or a notice where the following documents can be found:
 - Required by *HFS 157.88(1)*:
Chapter HFS 157 ‘Radiation Protection’ Subchapter III ‘Standards for Protection from Radiation’ and Subchapter X ‘Notices, Instructions and Reports to Workers’; license documents; operating procedures; DPH Form PPH 45027 ‘Notice to Employees’
- Development, distribution, implementation, and maintenance of up-to-date operating and emergency procedures
- Possession, installation, relocation, use, storage, repair, and maintenance of self-shielded irradiators are consistent with the limitations in the license, the SSD Registration Certificate(s), and manufacturer’s written recommendations and instructions
- Safety consequences are analyzed before conducting any activities involving repair, use, maintenance, installation, or relocation, which were never previously analyzed
- Individuals installing, relocating, using, maintaining, or repairing self-shielded irradiators are trained and authorized (as described in the license application)
- Prospective evaluations are performed demonstrating that individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits or personnel monitoring devices are provided
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained
- Self-shielded irradiators are properly secured
- Documentation is maintained to demonstrate, by measurement or calculation, that the TEDE to the individual member of the public likely to receive the highest dose from the licensed operation does not exceed the annual limit in *HFS 157.23(1)*

- Proper authorities are notified of incidents such as damage to or malfunction of self-shielded irradiators, fire, or theft
- Unusual occurrences involving the self-shielded irradiators (e.g., malfunctions or damage) are investigated, cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken
- Radiation safety program audits are performed at least annually and documented
- When the licensee identifies violations of **Chapter HFS 157 ‘Radiation Protection’** or license conditions or program weaknesses, the licensee develops, implements, and documents corrective actions
- Licensed material is transported in accordance with all applicable DOT requirements
- Licensed material is disposed of properly
- Appropriate records are maintained
- Up-to-date license is maintained and amendment and renewal requests are submitted in a timely manner

Appendix I

Information Needed to Support Applicant's Request to Perform Non-Routine Maintenance

Information Needed to Support Applicant's Request to Perform Non-routine Maintenance

Review **Item 9.8 'Maintenance'** which discusses, in general, licensee responsibilities before any maintenance or repair is performed.

Non-routine maintenance includes repairs, removal, replacement, or alterations involving:

- Electrical and mechanical systems and components that control source or shielding movement
- Self-shielded irradiator's shielding or sealed source(s)
- Safety interlocks
- Any other component which may affect safety operation of the device
- Any other activities during which personnel could receive radiation doses exceeding DHFS limits

See **Figure 9**. If this maintenance or repair is not performed properly with attention to radiation safety principles, the self-shielded irradiator may not operate as designed and personnel performing these tasks could receive radiation doses exceeding DHFS limits. Non-routine maintenance should be performed only by qualified and specifically authorized individuals. Self-shielded irradiator licensees should conduct these operations only after their procedures have been evaluated and specifically approved by license condition. Also, any non-manufacturer- (non-distributor-) supplied replacement components or the use of materials (e.g., lubricants) other than those specified or recommended by the manufacturer (or distributor) need to be evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the device registration. Licensees also need to ensure that, after maintenance or repair is completed, the irradiator is tested and functions as designed, before the unit is returned to routine use.

Accordingly, applicants wishing to perform non-routine maintenance must provide the following information, as appropriate:

- Describe the types of non-routine maintenance to be performed. The principal reason for obtaining this information is to assist in the evaluation of the qualifications of individuals who will conduct the work and the radiation safety procedures they will follow.

- Identify who will perform non-routine maintenance, their training and experience, and why they are competent to perform non-routine maintenance. Adequate training and experience includes the following:
 - Previous experience in non-routine maintenance and radiation safety training
 - Vender maintenance certification
 - Technician(s) using pre-planned procedures with direct health physics supervision

- Submit procedures for non-routine maintenance. These procedures should ensure the following:
 - Doses to personnel and members of the public are within regulatory limits and ALARA
 - The source is secured against unauthorized access or removal
 - Appropriate labels and signs are used
 - Manufacturer's (distributor's) written instructions and recommendations are followed
 - Any non-manufacturer (non-distributor) supplied replacement components or the use of materials (e.g., lubricants) other than those specified or recommended by the manufacturer (or distributor) are evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the device registration
 - Before being returned to routine use, the self-shielded irradiator is tested to verify that it functions as designed and source integrity is not compromised.

- Confirm that individuals performing non-routine maintenance on irradiators will always wear both whole body and extremity monitoring devices

- Verify possession of at least one instrument that meets the description for survey meters used with moving-source irradiators in “**Radiation Monitoring Instrument Specifications**” section of **Appendix K** in **WISREG 1556 Volume 5**. ‘*Guidance for Self-shielded Irradiators.*’

- Describe steps to be taken to ensure that radiation levels in areas where non-routine maintenance will take place do not exceed **HFS 157.23(1)** limits. For example, applicants can do the following:

- Commit to performing surveys with a survey instrument (as described above);
- Specify where and when surveys will be conducted during non-routine maintenance; and
- Commit to maintaining, for 3 years for the date of the survey, records of the survey (e.g., who performed the survey, date of the survey, instrument used, measured radiation levels correlated to location of those measurements), as required by ***HFS 157.31(3)***

Appendix J

Self-Shielded Irradiator Audit Checklist

Self-Shielded Irradiator Audit Checklist

Note: All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit. For example, licensees do not need to address areas which do not apply to the licensee's activities and activities which have not occurred since the last audit need not be reviewed at the next audit.

Date of This Audit

Date of Last Audit

Next Audit

Auditor:
(Signature)

Date

Management Review
(Signature)

Date

Audit History

- A. Were previous audits conducted annually? [*HFS 157.21*]
- B. Where records of previous audits maintained? [*HFS 157.31(2)*]
- C. Were any deficiencies identified during last two audits or two years, whichever is longer?
- D. Were corrective actions taken? (Look for repeated deficiencies).

Organization and Scope of Program

- A. Radiation Safety Officer
 - 1. If the RSO was changed, was license amended?
 - 2. Does new RSO meet DHFS training requirements?
 - 3. Is RSO fulfilling his/her duties?
 - 4. To whom does RSO report?
- B. Licensed Material

1. Does the license authorize all of the DHFS-regulated radioactive material contained in self-shielded irradiators?
 2. Does the total amount of radioactive material possessed require financial assurance?
[HFS 157.15]
- C. Are the self-shielded irradiators as described in the Sealed Source and Device (SSD) Registration Certificate? Have copies of (or access to) SSD Certificates? Have manufacturer's (or distributor's) manuals for operation and maintenance?
- D. Are the actual uses of self-shielded irradiators consistent with the authorized uses listed on the license?
- E. If the mailing address or places of use changed, was the license amended?
- F. If control of license transferred or bankruptcy filed, was DHFS prior consent obtained or notification made, respectively?

Training and Instructions to Workers

- A. Were all workers who are likely to exceed 1 mSv (100 mrem) in a year instructed per **HFS 157.88(2)**? Was refresher training provided, as needed [HFS 157.88(2)]?
- B. Did each authorized user and person independently performing routine or non-routine maintenance attend license-required training before working with self-shielded irradiators?
- C. Are training records maintained for each individual?
- D. Did interviews with workers reveal that they know the emergency procedures and repair, maintenance, and relocation limitations?
- E. Did this audit include observations of operators using the self-shielded irradiators? Performing routine or other authorized maintenance?
- F. Did the audit identify any operator error in reporting maintenance and repair or operation issues to the RSO for review before starting work?

Radiation Survey Instruments

- A. Describe the survey instruments possessed:
1. Do they meet the DHFS's criteria?
 2. Are they appropriate for the source type(s)?

3. Are they checked for function before use?
 4. If they are used with moving-source irradiators or during non-routine maintenance, are they calibrated as required? [**HFS 157.25(1)**]
- B. If the licensee does not possess a survey meter, are specific plans made to have one available?

Location: _____

Location/Operation verified: _____

- C. Are calibration records, if required, maintained? [**HFS 157.31(3)**]
- D. For J. L. Shepherd Mark I or Model 81-22 irradiator, check for compliance with license condition

Self-shielded Irradiator Inventory and Location

- A. Is a record kept showing the receipt of each self-shielded irradiator? [**HFS 157.13(18)**]
- B. Has the location(s) changed since the last audit?

Personnel Radiation Protection

- A. Are ALARA considerations incorporated into the radiation protection program? [**HFS 157.21**]
- B. Were prospective evaluations performed showing that unmonitored users receive $\leq 10\%$ of limit? [**HFS 157.25(2)**]
- C. Did unmonitored users' activities change during the year which could put them over 10% of limit?
- D. If yes to C above, was a new evaluation performed?
- E. Is external dosimetry required (users received $>10\%$ of limit)? Is dosimetry provided to users?
1. If processed dosimetry:
 - a. Is the dosimetry supplier NVLAP-approved? [**HFS 157.25(1)**]
 - b. Are dosimetry reports reviewed by the RSO when they are received?

2. If self-reading dosimeters:
 - a. Have a range of zero to at least 2 mSv (200 mrem)?
 - b. Are checked at periods not to exceed one year for correct response to radiation?
 - c. Are read within $\pm 20\%$ of the true radiation exposure?
 - d. Are used under a program that prescribes action to evaluate the individual's dose?
- F. Are the dosimeters exchanged or read at the license required frequency?
- G. Are the records DHFS Forms or equivalent? [*HFS 157.31(5 & 7)*]
 1. DPH Form 45003 '*Occupational Exposure Record per Monitoring Period*' completed?
- H. Declared pregnant worker/embryo/fetus
 1. If a worker declared her pregnancy, did licensee comply with *HFS 157.22(8)*?
 2. Were records kept of embryo/fetus dose per *HFS 157.31(7)*?
- I. Are records of exposures, surveys, monitoring, and evaluations maintained?
[*HFS 157.31(2-3 & 7)*]

Public Dose

- A. Are self-shielded irradiators located and used in a manner to keep doses below 1 mSv (100 mrem) in a year? [*HFS 157.23(1)*]
- B. Has a survey or evaluation been performed per *HFS 157.25(1)*?
- C. Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation?
- D. Do unrestricted area radiation levels exceed 0.02 mSv (2 mrem) in any one hour?
[*HFS 157.23(1)*]
- E. Are self-shielded irradiators being used or stored in a manner that would prevent unauthorized access or removal? [*HFS 157.28(1)(a)*]
- F. Records maintained? [*HFS 157.31(3,8)*]

Operating and Emergency Procedures

- A. Have operating and emergency procedures been developed?
- B. Do they contain the required element?
- C. Does each operator have a current copy of the operating and emergency procedures? Maintain copy at each irradiator's control panel or post notice indicating where to obtain copy?
- D. Did any emergencies occur?
 - 1. If so, were they handled properly by operator?
 - 2. Were appropriate corrective actions taken?
 - 3. Was DHFS notification or reporting required? [*HFS 157.32(1-3)*]
- E. For J. L. Shepherd Mark I or Model 81-22 irradiator, check for compliance with license condition
- F. Were operating or emergency procedures changed since last audit? If so, before new procedures were implemented:
 - 1. Did licensee management and the RSO approve?
 - 2. Did affected staff receive training?
 - 3. Are the changes consistent with license conditions? Licensee commitments?
 - 4. Do the changes degrade safety?

Leak Tests

- A. Was each sealed source leak tested every 6 months (or at other license prescribed intervals)?
- B. Was the leak test performed as described in correspondence with DHFS and according to the license?
- C. Are records of results retained with the appropriate information included?
- D. Were any sources found leaking and if yes, was DHFS notified?

Maintenance of Self-shielded Irradiators

- A. Are manufacturer's (or distributor's) written procedures followed for routine (not safety critical) cleaning and lubrication and mechanical/electrical maintenance and repair of self-shielded irradiators?
- B. Was non-routine maintenance performed?
- C. If yes, was it performed according to license requirements (e.g., extent of work, individuals performing the work, procedures, dosimetry, survey instrument, compliance with dose limits)?
- D. Since the last audit, did operator(s) report a need for non-routine maintenance and repair to the RSO before requesting or conducting the work?

Transportation

- A. Were self-shielded irradiator(s) or sources shipped since the last audit?
- B. If so, was **Chapter HFS 157 'Radiation Protection' Subchapter XIII 'Transportation'** requirements followed?
 - 1. DOT-Type A or Type B packages used?[**Chapter HFS 157 'Radiation Protection' Subchapter XIII; 49 CFR 173.415; 49 CFR 173.416(b)**] If Type B, NRC Certificate of Compliance granted before shipment or shipper is registered as a user of the Type B package? DHFS-approved QA program?
 - 2. Package performance test records on file? [**49 CFR 173.415**]
 - 3. Special form sources documentation? [**49 CFR 173.476(a)**]
 - 4. Package has 2 labels (ex. Yellow-II) with TI, Nuclide, Activity, and Hazard Class? [**49 CFR 172.403; 49 CFR 173.441**]
 - 5. Package properly marked? [**49 CFR 172.301; 49 CFR 172.304; 49 CFR 172.310; 49 CFR 172.324**]
 - 6. Package closed and sealed during transport? [**49 CFR 173.475(f)**]
 - 7. Shipping papers prepared, used, and maintained? [**49 CFR 172.200(a)**]
 - 8. Shipping papers contain proper entries? {Shipping name, Hazard Class, Identification Number (UN Number), Total Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity (SI units required), Category of Label, TI, Shipper's Name, Certification and Signature, Emergency Response Phone Number, Cargo Aircraft Only (If applicable)} [**49 CFR 172.200; 49 CFR 172.201; 49 CFR 172.202; 49 CFR 172.203; 49 CFR 172.204; 49 CFR 172.604**]
 - 9. Secured against movement? [**49 CFR 177.834**]

10. Placarded on vehicle, if needed? [*49 CFR 172.504*]
11. Proper overpacks, if used? [*49 CFR 173.25*]
12. Any incidents reported to DOT? [*49 CFR 171.15; 49 CFR 171.16*]
13. Irradiators manufactured before 1966
 - a. Where any shipped?
 - b. Were DHFS and DOT exemptions, if needed, received in advance?

Auditor's Independent Survey Measurements (If Made)

- A. Describe the type, location, and results of measurements.
- B. Do any radiation levels exceed regulatory limits?

Notifications and Reports

- A. Was any radioactive material lost or stolen? Were reports made?
[*HFS 157.32(1); HFS 157.13(17)*]
- B. Did any reportable incidents occur? Were reports made? [*HFS 157.32(2); HFS 157.13(17)*]
- C. Did any overexposures and high radiation levels occur? Reported?
[*HFS 157.32(3); HFS 157.13(17)*]
- D. If any events (as described in 1 through 3 above) did occur, what was root cause? Were corrective actions appropriate?
- E. Is the licensee aware of 24-hr DHFS emergency telephone number [(608) 258-0099]?

Posting and Labeling

- A. DHFS's 'Notice to Employees' posted? [*HFS 157.88(1)*]
- B. Chapter HFS 157 'Radiation Protection', license documents posted or a notice posted?
[*HFS 157.88(2)*]
- C. Other posting and labeling? [*HFS 157.29(2 & 4)*]

Record Keeping for Decommissioning

- A. Records kept of information important to decommissioning? [*HFS 157.15*]
- B. Records include all information outlined in *HFS 157.15*?

Bulletins and Information Notices

- A. DHFS Bulletins, DHFS Information Notices received?
- B. Appropriate training and action taken in response?

Special License Conditions or Issues

- A. Did auditor review any special license conditions?
- B. Did auditor review any other issues (e.g., non-routine maintenance)?

Deficiencies Identified in Audit; Corrective Actions

- A. Summarize problems/deficiencies identified during audit.
- B. If problems/deficiencies identified in this audit, describe corrective actions planned or taken. Include date(s) when corrective actions are implemented.
- C. Provide any other recommendations for improvement.

Evaluation of Other factors

- A. Senior licensee management is appropriately involved with the radiation protection program and/or Radiation Safety Officer (RSO) oversight?
- B. RSO has sufficient time to perform his/her radiation safety duties?
- C. Licensee has sufficient staff to support the radiation protection program?

Appendix K

Radiation Monitoring Instrument Specifications and Survey Instrument Calibration Program

Instrument(s) used with moving-source gamma irradiators must meet the following criteria:

- The instrument is a survey meter capable of detecting gamma radiation of more than 5×10^{-5} coulombs/kilogram (C/kg) (or up to several hundred milliroentgens (mR)) per hour which is:
 - In the licensee's possession
 - Checked with a source of radiation at the beginning of each day of use to ensure that it will respond consistently to radiation
 - Calibrated with a source of radiation annually and after any servicing or repair (other than a simple battery exchange), ensure that exposure rates indicated by the meter do not vary from the actual exposure rates by more than $\pm 20\%$. Calibrations must be performed by the instrument manufacturer or a person specifically authorized by DHFS, the NRC, or another Agreement State.

OR

- The instrument is a room monitor which:
 - Is in the licensee's possession
 - Is checked with a source of radiation at the beginning of each day of use to ensure that it will respond accurately to radiation and alarm at 0.02 mSv (2 mrem) per hour
 - Activates a visible and audible alarm when radiation levels exceed 0.02 mSv (2 mrem) per hour
 - Is positioned so it will detect any radiation escaping from the irradiator door yet still be visible to the irradiator operator when using the irradiator.

Instrument(s) used with fixed-source gamma irradiators (or beta irradiators) are:

- A survey meter capable of detecting gamma radiation (or beta radiation, as appropriate)
- In the licensee's possession or readily accessible in the event of an accident or malfunction which could reduce the shielding for the sealed source(s)
- Checked with a source of radiation at the beginning of each day of use to ensure that it will respond consistently to radiation
- Calibrated with a source of radiation annually and after any servicing or repair (other than a simple battery exchange), to ensure that exposure rates indicated by the meter do not vary from the actual exposure rates by more than $\pm 20\%$. Calibrations must be performed by the instrument manufacturer or a person specifically authorized by DHFS, the NRC or another Agreement State.

Survey Instrument Calibration Program

Training

Before allowing an individual to perform survey instrument calibrations, the RSO will ensure that the individual has sufficient classroom and on-the-job training to show competency in performing independent survey instrument calibrations.

Classroom training may be in the form of lecture, videotape, or self-study and will cover the following subject areas:

- Principles and practices of radiation protection
- Radioactivity measurements, monitoring techniques, and using instruments

- Mathematics and calculations basic to using and measuring radioactivity
- Biological effects of radiation.

Appropriate on-the-job training consists of:

- Observing authorized personnel performing survey instrument calibration
- Conducting survey meter calibrations under the supervision and in the physical presence of an individual authorized to perform calibrations.

Facilities and Equipment

- To reduce doses received by individuals not calibrating instruments, calibrations will be conducted in an isolated area of the facility or at times when no one else is present
- Individuals conducting calibrations will wear assigned dosimetry
- Individuals conducting calibrations will use a calibrated and operable survey instrument to ensure that unexpected changes in exposure rates are identified and corrected.

Procedures for Calibrating Survey Instruments for Gamma Detection

- A radioactive sealed source(s) used for calibrating survey instruments will:
 - Approximate a point source
 - Have its apparent source activity or the exposure rate at a given distance traceable by documented measurements to a standard certified to be within $\pm 5\%$ accuracy by NIST

- Approximately the same photon energy (Cs-137, Co-60) as the environment in which the calibrated device will be employed
- Be strong enough to give an exposure rate of at least 7.7×10^{-6} C/kg/hr (or 30 mR/hr) at 100 cm [e.g., 3.1 GBq (85 mCi) of Cs-137) or 7.8×10^2 MBq (21 mCi) of Co-60].
- The inverse square and radioactive decay laws must be used to correct changes in exposure rate due to changes in distance or source decay.
- A record must be made of each survey meter calibration and retained for 3 years after each record is made (*HFS 157.31(3)*)
- A single point on a survey meter scale may be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than $\pm 20\%$
- The three kinds of scales frequently used on radiation survey meters are calibrated either as described in ANSI N323A-1996, “American National Standard Radiation Protection Instrumentation Test and Calibration- Portable Survey Instruments,” or as follows:
 - Meters on which the user selects a linear scale must be calibrated at not fewer than two points on each scale. The points will be at approximately 1/3 and 2/3 of the decade.
 - Meters that have a multidecade logarithmic scale must be calibrated at one point (at the least) on each decade and not fewer than two points on one of the decades. Those points will be approximately 1/3 and 2/3 of the decade
 - Meters that have an automatically ranging digital display device for indicating exposure rates must be calibrated at one point (at the least) on each decade and at no fewer than two points on one of the decades. Those points will be approximately 1/3 and 2/3 of the decade.

- Readings above 2.58×10^{-4} C/kg/hr (1000 mR/hr) need not be calibrated. However, such scales should be checked for operation and approximately correct response.
- Survey meter calibration reports will indicate the procedure used and the data obtained. The description of the calibration will include:
 - The owner or user of the instrument
 - A description of the instrument including the manufacturer's name, model number, serial number, and type of detector
 - A description of the calibration source, including the exposure rate at a specified distance on a specified date, and the calibration procedure
 - For each calibration point, the calculated exposure rate, the indicated exposure rate, the deduced correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument
 - The exposure reading indicated with the instrument in the "battery check" mode (if available on the instrument)
 - For instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular)
 - For instruments with internal detectors, the angle between radiation flux field and a specified surface of the instrument
 - For detectors with removable shielding, and indication whether the shielding was in place or removed during the calibration procedure
 - The exposure rate from a check source, if used

- The person's name who performed the calibration and date it was performed
- The following information will be attached to the instrument as a calibration sticker or tag:
 - The source that was used to calibrate the instrument
 - The proper deflection in the battery check mode (unless this is clearly indicated on the instrument)
 - For each scale or decade not calibrated, an indication that the scale or decade was checked on for function but not calibrated
 - The date of calibration and the next calibration due date
 - The apparent exposure rate from the check source, if used.

References: Detailed information about survey instrument calibration may be obtained by referring to ANSI N323A-1996, "American National Standard Radiation Protection Instrumentation Test and Calibration - Portable Survey Instruments." Copies may be ordered electronically at <<http://www.ansi.org>> or by writing to ANSI, 1430 Broadway, New York, NY 10018.

See Section 8.10.2 and Appendix J of NRC NUREG 1556 Vol. 18 "Program Specific Guidance about Service Provider Licenses," and is available electronically at NRC's web site, <http://www.nrc.gov>, under "Electronic Reading Room," then "All Collections," the "NUREG-Series Publications."

Appendix L

Guidance for Demonstrating That Unmonitored Individuals Are Not Likely to Exceed 10 Percent of the Allowable Limits

Dosimetry is required for individuals likely to receive, in 1 year from sources external to the body, a dose in excess of 10% of the applicable regulatory limits in *HFS 157.22(1)*. To demonstrate that dosimetry is not required, a licensee needs to perform a prospective evaluation to demonstrate that its workers are not likely to exceed 10% of the applicable annual limits.

The most common way that individuals might exceed 10% of the applicable limits is by performing frequent routine maintenance on the irradiator. However, for most new irradiators even these activities result in the individual's receiving minimal doses. Before allowing workers to perform these tasks, a licensee will need to evaluate the doses which its workers might receive to assess whether dosimetry is required; this is a prospective evaluation.

Example

The following is an example of an estimate of the dose received by the extremities and whole body of a person performing routine maintenance (cleaning and lubrication) on a self-shielded irradiator rotating drawer drive chain. The estimate is based on observations of individuals performing the recommended procedure according to good radiation safety practices. The manufacturer can provide the following types of information:

- Time needed to perform the entire procedure (e.g., 20 min)
- Extremity dose rate received by an individual, associated with the shielded source (e.g., 0.02 mSv/hr [2 mrem/hr] at contact with the shield)
- Time the hands were exposed to the shielded source (e.g., 3 min)
- Whole body dose rate received by an individual, associated with the shielded source (e.g., 0.01 mSv/hr [1 mrem/hr] at contact with the shield)
- Time the whole body is exposed to the shielded source (e.g., 20 min)

From this information, an estimate of the doses that the individual performing this procedure could receive is as follows:

- 0.001 mSv [0.1 mrem] to the hands

- Less than 0.0033 mSv [0.33 mrem] TEDE (whole body).

The applicable TEDE (whole body) limit is 50 mSv (5 rems) per year and 10% of that value is 5 mSv (500 mrem) per year. If one of these procedures delivers 0.0033 mSv (0.33 mrem), then an individual could perform 1,515 of these procedures each year and remain within 10% of the applicable limit.

The applicable shallow-dose equivalent (SDE) (extremities) is 500 mSv (50 rems) per year and 10% of that value is 50 mSv (5 rems or 5000 mrem) per year. If one of these procedures delivers 0.001 mSv (0.1 mrem), then an individual could perform 50,000 of these procedures each year and remain within 10% of the applicable limit.

Based on the above specific situation, no dosimetry is required if a worker performs fewer than 1,515 routine maintenance procedures per year.

Guidance to Licensees

Licensees who wish to demonstrate that they are *not* required to provide dosimetry to their workers need to perform prospective evaluations similar to that shown in the example above. The expected dose rates, times, and distances used in the above example may *not* be appropriate to individual licensee situations. In their evaluations, licensees need to use information appropriate to the type(s) of self-shielded irradiator(s) they intend to use; this information is generally available from the irradiator manufacturer (or distributor) or the SSD Registration Certificate maintained by the NRC and Agreement States.

Table 5 may be helpful in performing a prospective evaluation.(5)

| |
|--|
| <p>Note: For ease of use by most irradiator licensees, this table uses conventional units. The conversion to SI units is: 1 mrem = 0.01 mSv]</p> |
|--|

Licensees should review evaluations periodically and revise them as needed. Licensees need to check assumptions used in their evaluations to ensure that they continue to be up-to-date and accurate. For example, if workers become lax in following good radiation safety practices, perform the task more slowly than estimated, work with new irradiators containing sources of different activities or radionuclides, or use modified procedures, the licensee would need to conduct a new evaluation.

Table 5. Dosimetry Evaluation

| Dosimetry Evaluation for : | | Model: | Self-Shielded Irradiator | |
|----------------------------|--|--------|--------------------------|-----------|
| A. | Time needed to perform the entire routine maintenance procedure. | | _____ (minutes/60) | ____ hour |
| B. | Expected whole body dose rate received by the individual, determined using exposure rates measured on contact with the irradiator while the sealed source is in the shielded position. | | ____ mrem/hr | |
| C. | Time the hands were exposed to the unshielded source. | | _____ (minutes/60) | ____ hour |
| D. | Expected extremity dose rate received by the individual, determined using exposure rates measured at the typical distance that the hands would be from the sealed source during the routine maintenance procedure. | | ____ mrem/hr | |

Formula: (____ # hours in Row A) x (____ mrem/hr in Row B) = (____ mrem per routine procedure) x (____ # of routine maintenance procedure each year) = ____ mrem * Whole Body Dose

Formula: (____ # hours in Row C) x (____ mrem/hr in Row D) = (____ mrem per routine procedure) x (____ # of routine maintenance procedures each year) = ____ mrem ** Extremity Dose

* Expected Whole Body Doses less than 500 mrem requires no dosimetry

** Expected Extremity Doses less than 5000 mrem requires no dosimetry

Appendix M

Guidance for Demonstrating That Individual Members of the Public Will Not Receive Doses Exceeding the Allowable Limits

Licensees must ensure that:

- The radiation dose received by individual members of the public does not exceed 1 mSv (100 mrem) in one calendar year resulting from the licensee's possession and/or use of licensed materials.

Members of the public include persons who live, work, or may be near locations where self-shielded irradiator devices are used or stored and employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where irradiators are used or stored.

- The radiation dose in unrestricted areas does not exceed 0.02 mSv (2 mrem) in any one hour.

Typical unrestricted areas may include offices, shops, laboratories, areas outside buildings, property, and nonradioactive equipment storage areas. The licensee does not control access to these areas for purposes of controlling exposure to radiation or radioactive materials. However, the licensee may control access to these areas for other reasons such as security.

Licensees must show compliance with both portions of the regulation. For areas around self-shielded irradiator facilities, calculations or a combination of calculations and measurements (e.g., using an environmental TLD) are often used to prove compliance.

Calculational Method

The calculational method takes a tiered approach, going through a three-part process starting with a worst case situation and moving toward more realistic situations. It makes the following simplifications: (1) each irradiator is a point source; (2) typical radiation levels encountered when the source is in the shielded position are taken from either the SSD Registration Certificate, ANSI N433.1, (7) [Note: 7. Copies may be ordered electronically at <http://www.ansi.org> or by writing to ANSI, 1430 Broadway, New York, NY 10018. Copies are also available from the NTIS, 5285 Port Royal Road, Springfield, VA 22161 1-800-553-6847.] "Safe Design and Use of Self-Contained, Dry Source Storage Gamma Irradiator (Category I)," or the manufacturer's (or distributor's)

literature; and (3) no credit is taken for any shielding found between the irradiator and the unrestricted areas.

Part 1 of the calculational method is simple but conservative. It assumes that an affected member of the public is present 24 hours a day and uses only the inverse square law to determine if the distance between the irradiator and the affected member of the public is sufficient to show compliance with the public dose limits. **Part 2** considers not only distance, but also the time that the affected member of the public is actually in the area under consideration. **Part 3** considers the distance, the portion of time and dose rate while the sample is in transit, the portion of time and dose rate while the sample is not in transit, and the portion of time that the affected member of the public is present. Using this approach, licensees make only those calculations that are needed to demonstrate compliance. In many cases licensees will need to use the calculational method through **Part 1** or **Part 2**. The results of these calculations typically result in higher radiation levels than would exist at typical facilities, but provide a conservative method for estimating doses which could be received.

Example 1

To better understand the calculational method, we will examine Bugs-Away, Inc., a self-shielded irradiator licensee. Yesterday, the company's president noted that the new irradiator area is close to his secretary's desk and he asked Joe, the Radiation Safety Officer (RSO), to determine if the company is complying with **Chapter HFS 157 'Radiation Protection'**.

The secretary's desk is near the wall separating the reception area from the designated, locked self-shielded irradiator room where the company has located its irradiator. Joe measures the distance from the self-shielded irradiator to the wall and assumes that the irradiator would have the maximum dose rate allowed under ANSI N433.1: 10 mrem per hour at one meter. This is the maximum dose rate permitted while the sample is in transit (i.e., moving into or out of the irradiation position). **Figure 10** is Joe's sketch of the areas in question, and **Table 6** summarizes the information Joe has on the irradiator.

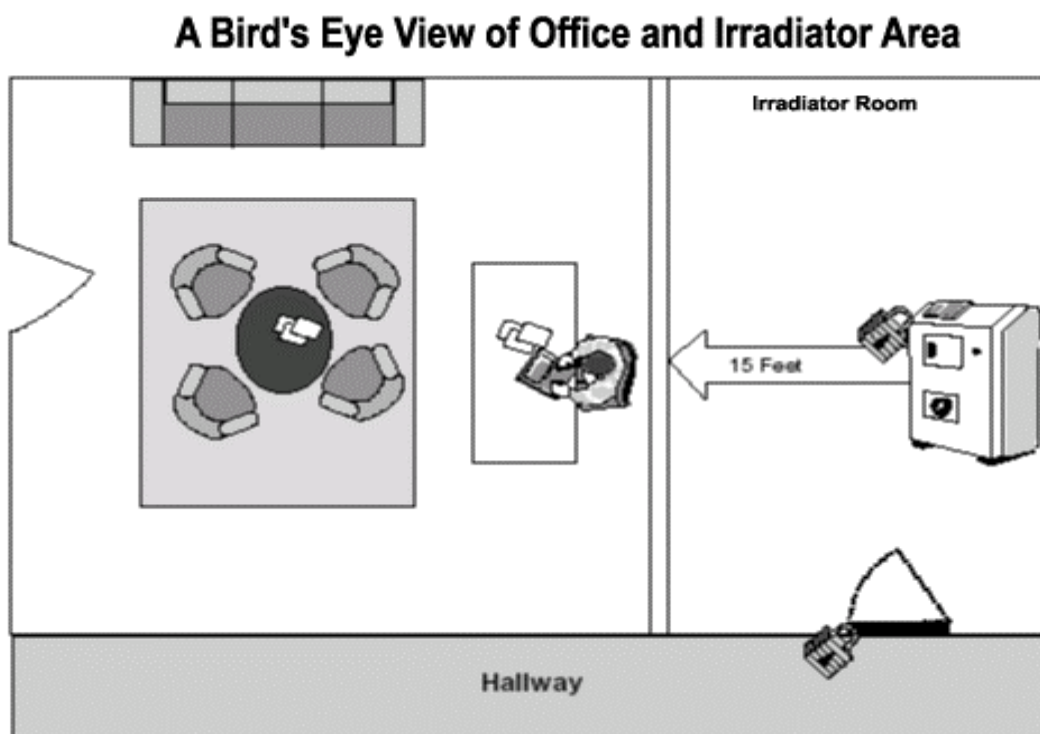


Figure 10. Diagram of Office and Irradiator Area. This sketch shows the areas described in Examples 1 and 2.

Table 6. Information Known about the Self-Shielded Irradiator

| Description of Known Information | Cs-137 Self-Shielded Irradiator |
|---|---------------------------------|
| Dose rate in mrem/hr encountered at specified distance from the irradiator (from ANSI N433.1) | 10 mrem/hr at 1 meter (3.28 ft) |
| Distance in feet to secretary's chair | 15 ft |

Example 1: Part 1

Joe's first thought is that the distance between the irradiator and the secretary's chair may be sufficient to show compliance with the regulation in *HFS 157.23(1)*. So, taking a worst case approach, he assumes: 1) the self-shielded irradiator is constantly present (i.e., 24 hr/d) with the samples constantly in transit, and 2) the secretary is constantly sitting in the desk chair (i.e., 24 hr/d). Joe proceeds to calculate the dose she might receive hourly and yearly from the self-shielded irradiator as shown in **Table 7** below.

Table 7. Calculational Method, Part 1: Hourly and Annual Dose Received from Self-Shielded Irradiator

| Step No. | Description | Input Data | Result |
|----------|--|---------------------|---------------------------------|
| 1 | Dose received in an hour at known distance from irradiator (e.g., from ANSI N433.1), in mrem/hr | 10 | 10 |
| 2 | Square of the distance (ft) at which the Step 1 rate was measured, in ft ² | (3.28) ² | 10.8 |
| 3 | Square of the distance (ft) from the irradiator to the secretary's desk in an unrestricted area in ft ² | (15.0) ² | 225 |
| 4 | Multiply the results of Step 1 by the results of Step 2 (this is an intermediate result) | 10 x 10.8 | 108 (rounded to 110) |
| 5 | Divide the results of Step 4 by the result of Step 3 to calculate the dose received by an individual at the secretary's desk, HOURLY DOSE RECEIVED FROM SELF-SHIELDED IRRADIATOR , in mrem in an hour | 110/225 | 0.48 |
| 6 | Multiply the result of Step 5 by 24 hr/d x 366 (leap year) d/yr = MAXIMUM ANNUAL DOSE RECEIVED FROM SELF-SHIELDED IRRADIATOR , in mrem in a year | 0.48 x 24 x 366 | 4200 |

Note: The result in Step 5 demonstrates compliance with the 2 mrem in any one hour limit, Reevaluate if assumption change. If the result in Step 6 exceeds 100 mrem/yr, proceed to Part 2 of the calculational method.

At this point, Joe is pleased to see that the total dose that an individual could receive in any one hour is only 0.48 mrem, but notes that an individual could receive a dose of 4,200 mrem in a year, much higher than the 100 mrem limit.

Example 1: Part 2

Joe reviews his assumptions and recognizes that the secretary is not at the desk 24 hr/d. He decides to make a realistic estimate of the number of hours the secretary sits in the chair at the desk, keeping

his other assumptions constant (i.e., the self-shielded irradiator is constantly present (i.e., 24 hr/d) with the samples constantly in transit). He then recalculates the annual dose received.

Table 8. Calculational Method, Part 2: Annual Dose Received from Self-Shielded Irradiator

| Step No. | Description | Result |
|----------|---|---|
| 7 | A. Average number of hours per day that individual spends in area of concern (e.g., secretary sits at desk 5 hr/d; the remainder of the day the secretary is away from the desk area copying, filing, etc.) | 5.0 |
| | B. Average number of days per week in area (e.g., secretary is part time and works 3 d/wk) | 3.0 |
| | C. Average number of weeks per year in area (e.g., secretary works all year) | 52 |
| 8 | Multiply the results of Step 7.A by the results of Step 7.B. by the results of Step 7.C. = AVERAGE NUMBER OF HOURS IN AREA OF CONCERN PER YEAR | $5.0 \times 3.0 \times 52 = \mathbf{780}$ |
| 9 | Multiply the results in Step 5 by the results of Step 8 = ANNUAL DOSE RECEIVED FROM IRRADIATOR CONSIDERING REALISTIC ESTIMATE OF TIME SPENT IN AREA OF CONCERN , in mrem in a year | $0.48 \times 780 = \mathbf{370}$ |

Note: If Step 9 exceeds 100 mrem in a year, proceed to Part 3 of the calculational method.

Although Joe is pleased to note that the calculated annual dose received is significantly lower, he realizes it still exceeds the 100 mrem in a year limit.

Example 1: Part 3

Again Joe reviews his assumptions and recognizes that the irradiator is not constantly in use nor is the sample continuously in transit during an irradiation cycle when the secretary is seated at the desk. As he examines the situation, he realizes he must take these factors into account.

Table 9. Calculational Method, Part 3: Summary of Information

| Step No. | Description | Input |
|----------|---|-------|
| 10 | Dose rate while the irradiator is idle, in mrem/hr at 3.28 ft from the irradiator | 2.0 |
| 11 | Dose rate while the same is in transit, in mrem/hr at 3.28 ft from the irradiator | 10. |
| 12 | Dose rate while sample is irradiated, in mrem/hr at 3.28 ft from the irradiator | 2.0 |
| 13 | Maximum number of irradiations per hour | 5.0 |
| 14 | Maximum irradiation time, in min | 3.0 |
| 15 | Time that the same is in transit, in min per irradiation cycle | 0.20 |
| 16 | From Table 6 , distance from irradiator to secretary, in ft | 15 |
| 17 | From Step 8, average number of hours that secretary is in area of concern, per year | 780 |

Table 10. Calculational Method, Part 3: Annual Dose Received from Irradiator

| Step No. | Description | Result |
|----------|--|--------------|
| 18 | [60 minus the input from Step 13 multiplied by (the input from Step 14 plus the input from Step 15) divided by 60 = $[60. - 5.0 \times (3.0 + 0.20)] / 60. = [60. - 16.] / 60 =$ FRACTION OF TIME THE IRRADIATOR IS IDLE | 0.73 |
| 19 | (The input from Step 13 multiplied by the input from Step 15) divided by 60 = $(5.0 \times 0.20) / 60 = 1/60 =$ FRACTION OF TIME THE SAMPLE IS IN TRANSIT | 0.017 |
| 20 | 1.0 minus the result from Step 18 minus the result from Step 19 = $1 - 0.73 - 0.017 =$ FRACTION OF TIME THE IRRADIATOR IS IN USE | 0.253 |
| 21 | (The input from Step 10 multiplied by the result from Step 18) plus (the input from Step 11 multiplied by the result from Step 19) plus (the input from Step 12 multiplied by the result from Step 20) = $(2.0 \times 0.73) + (10. \times 0.017) + (2.0 \times 0.253) = 1.46 + 0.17 + 0.506 =$ AVERAGE DOSE RATE ENCOUNTERED AT 3.28 FEET FROM THE IRRADIATOR, in mrem in an hour | 2.136 |

| Step No. | Description | Result |
|----------|---|-------------|
| 22 | The result from Step 21 multiplied by (3.28 squared divided by the input from Step 16 squared) = $2.136 \times (3.28^2 / 15^2) = 2.136 \times (10.8/225) = \text{AVERAGE DOSE RATE ENCOUNTERED BY THE SECRETARY, in mrem per hour}$ | 0.10 |
| 23 | The result from Step 22 multiplied by the input from Step 17 = $780 \times 0.10 = \text{ANNUAL DOSE RECEIVED FROM IRRADIATOR CONSIDERING REALISTIC ESTIMATES FOR TIME SPENT IN AREA OF CONCERN, DOSE RATES, AND IRRADIATOR USAGE, in mrem in a year}$ | 78. |

Note: If the result in Step 23 is greater than 100 mrem/yr, the licensee must take corrective actions

Joe is glad to see that the results in Step 23 show compliance with the 100 mrem in a year limit. Had the result in Step 23 been higher than 100 mrem in a year, then Joe could have done one or more of the following:

- Consider whether the assumptions used to determine occupancy are accurate, revise the assumptions as needed, and recalculate using the new assumptions
- Calculate the effect of any shielding (8) located between the irradiator area and the secretarial workstation -- such calculation is beyond the scope of this Appendix [Note: 8. National Council on Radiation Protection and Measurements (NCRP) Report No. 49, "Structural Shielding Design and Evaluation for Medical Use of X Rays and Gamma Rays of Energies Up to 10 MeV," contains helpful information. It is available from NCRP, 7910 Woodmont Avenue, Suite 800, Bethesda, Maryland 20814. NCRP's telephone numbers are: (301) 657-2652 or 1-800-229-2652.]
- Take corrective action (e.g., move irradiator within the use area, move the use area, move the secretarial workstation) and perform new calculations to demonstrate compliance
- Designate the area outside the use area as a restricted area and the secretary as an occupationally exposed individual. This would require controlling access to the area for purposes of radiation protection and training the secretary.

Note that in the example, Joe evaluated the unrestricted area outside only one wall of the irradiator area. Licensees also need to make similar evaluations for other unrestricted areas and to keep in mind the ALARA principle, taking reasonable steps to keep radiation dose received below regulatory requirements. In addition, licensees need to be alert to changes in situations (e.g., moving the self-shielded irradiator closer to the secretarial workstation, adding a second irradiator, changing the secretary to a full-time worker, or changing the estimate of the portion of time spent at the desk) and to perform additional evaluations, as needed.

| |
|--|
| RECORDKEEPING: <i>HFS 157.31(8)</i> requires licensees to maintain records demonstrating compliance with the dose limits for individual members of the public. |
|--|

Combination Measurement-Calculational Method

This method, which allows the licensee to take credit for shielding between the irradiator and the area in question, begins by measuring radiation levels in the areas, as opposed to using ANSI-N433.1 or manufacturer- (or distributor-) supplied rates at a specified distance from each irradiator. These measurements must be made with calibrated survey meters sufficiently sensitive to measure background levels of radiation. However, licensees must exercise caution when making these measurements, and they must use currently calibrated radiation survey instruments. A maximum dose of 1 mSv (100 mrem) received by an individual over a period of 2080 hours (i.e., a "work year" of 40 hr/wk for 52 wk/yr) is equal to less than 0.5 microsievert (0.05 mrem) per hour.

| |
|--|
| This rate is well below the minimum sensitivity of most commonly available G-M survey instruments. |
|--|

Instruments used to make measurements for calculations must be sufficiently sensitive. An instrument equipped with a scintillation-type detector (e.g., NaI(Tl)) or a micro-R meter used in making very low gamma radiation measurements should be adequate.

Licensees may also choose to use environmental TLDs (See Note) in unrestricted areas next to the irradiator area for monitoring. This direct measurement method would provide a definitive measurement of actual radiation levels in unrestricted areas without any restrictive assumptions.

Records of these measurements can then be evaluated to ensure that rates in unrestricted areas do not exceed the 1 mSv/yr (100 mrem/yr) limit.

NOTE: TLDs used for personnel monitoring (e.g., LiF) may not have sufficient sensitivity for this purpose. Generally, the minimum reportable dose received is 0.1 mSv (10 mrem). Suppose a TLD monitors dose received and is changed once a month. If the measurements are at the minimum reportable level, the annual dose received could have been about 1.2 mSv (120 mrem), a value in excess of the 1 mSv/yr (100 mrem/yr) limit. If licensees use TLDs to evaluate compliance with the public dose limits, they should consult with their TLD supplier and choose more sensitive TLDs, such as those containing CaF_2 that are used for environmental monitoring.]

Example 2

As in Example 1, Joe is the RSO for Bugs-Away, Inc., a self-shielded irradiator licensee. The company has one irradiator in a designated, locked area that adjoins an unrestricted area where a secretarial workstation is located. See **Figure 10** and **Table 6** for information. Joe wants to see if the company complies with the public dose limits at the secretarial station.

Joe placed an environmental TLD badge in the secretarial work space for 30 days. The TLD processor sent Joe a report indicating the TLD received 100 mrem.

Table 11. Combination Measurement-Calculational Method

| Step No. | Description | Input Data and Results |
|---|--|--|
| Part 1 | | |
| 1 | Dose received by TLD, in mrem | 100 |
| 2 | Total hours TLD exposed | 24 hr/d x 30 d/mo = 720 |
| 3 | Divide the results of Step 1 by the results of Step 2 = HOURLY DOSE RECEIVED , in mrem in an hour | 100/720 = 0.14 |
| 4 | Multiply the results of Step 3 by 366 d/yr [leap year] x 24 hr/d = 8784 hours in one year = MAXIMUM ANNUAL DOSE RECEIVED FROM IRRADIATOR , in mrem in a year | 366 x 24 x 0.14 = 8784 x 0.14 = 1230 |
| <p>Note: For the conditions described above, Step 3 indicates that the dose received in any one hour is less than the 2 mrem in any one hour limit. However, if there are any changes, then the licensee would need to reevaluate the potential doses which could be received in any one hour. Step 4 indicates that the annual dose received would be much greater than the 100 mrem in a year allowed by the regulations</p> | | |
| Part 2 | | |
| At this point Joe can adjust for a realistic estimate of the time the secretary spends in the area as he did in Part 2 of Example 1. | | |
| Part 3 | | |
| If the results of Joe's evaluation in Part 2 show that the annual dose received in a year exceeds 100 mrem, then he may have to consider moving the self-shielded irradiator or the secretary's desk, or adding shielding to the wall. | | |

Appendix N

Typical DHFS Incident Notifications Required for Self-Shielded Irradiator Licensees

Table 12 Typical DHFS Incident Notifications Required for Self-Shielded Irradiator Licensees

| Event | Telephone Notification | Written Report | Rule Requirement |
|---|-------------------------------|-----------------------------------|--------------------------|
| Theft or lost of material | Immediate | 30 days | <i>HFS 157.32(1)</i> |
| Whole body dose greater than 0.25 Sv (25 rems) | Immediate | 30 days | <i>HFS 157.32(2)</i> |
| Extremity dose greater than 2.5 Sv (250 rems) | Immediate | 30 days | <i>HFS 157.32(2)</i> |
| Whole body dose greater than 0.05 Sv (5 rems) in 24 hours | 24 hours | 30 days | <i>HFS 157.32(2)</i> |
| Extremity dose greater than 0.5 Sv (50 rems) in 24 hours | 24 hours | 30 days | <i>HFS 157.32(2)</i> |
| Whole body dose greater than 0.05 Sv (5 rems) | None | 30 days | <i>HFS 157.32(3)</i> |
| Dose to individual member of public greater than 1 mSv (100 mrem) | None | 30 days | <i>HFS 157.32(3)</i> |
| Filing petition for bankruptcy under 11 U.S.C. | None | Immediately after filing petition | <i>HFS 157.13(10)(e)</i> |
| Expiration of license | None | 60 days | <i>HFS 157.13(11)(d)</i> |
| Decision to permanently cease license activities at <i>entire site</i> | None | 30 days | <i>HFS 157.13(10)(d)</i> |
| Decision to permanently cease licensed activities in any separate building or outdoor area that is unsuitable for release for unrestricted use. | None | 60 days | <i>HFS 157.13(11)(d)</i> |
| No principal activities conducted for 24 months at the entire site | None | 60 days | <i>HFS 157.13(11)(d)</i> |
| No principal activities conducted for 24 months in any separate building or outdoor area that is unsuitable for release for unrestricted use | None | 60 days | <i>HFS 157.13(11)(d)</i> |
| Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits | Immediate | 30 days | <i>HFS 157.13(17)</i> |

| Event | Telephone Notification | Written Report | Rule Requirement |
|---|------------------------|----------------|-----------------------|
| Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits | 24 hours | 30 days | <i>HFS 157.13(17)</i> |
| Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material | 24 hours | 30 days | <i>HFS 157.13(17)</i> |

Note: Telephone notifications shall be made to the DHFS at (608) 267-4797 (during office hours) or (608) 258-0099 (24-hour emergency number) if an emergency.

Appendix O

Information for Applicants to Consider When Developing Operating and Emergency Procedures for Self-Shielded Irradiators

Elements of Operating Procedures Applicable to All Types of Self-Shielded Irradiators

- Analyze each type of material to be placed in the irradiator to ensure that it is comparable with the irradiator's design or to determine whether special procedures in addition to those given by the manufacturer (or distributor) are required to ensure the safe operation of the irradiator.
- Prepare model-specific instructions for routine inspections, test procedures, and maintenance to ensure that all interlocks, devices, and components critical to the safe operation of the irradiator are functioning properly. (Prohibited actions such as changing the safety control system or removing the source should be stated.)
- Develop methods to maintain accountability (e.g., logbook to record irradiator use) and to ensure that only authorized persons will use or have access to the irradiator (e.g., control access to the irradiator's keys or control access to the area where the irradiator is located).
- Define steps to take to keep radiation exposures ALARA
- For each model irradiator, define step-by-step procedures on how to operate the irradiator and how to perform routine maintenance. Information may be extracted from the manufacturer's (or distributor's) manual.

Specific Operating Procedures Applicable to Moving-Source Irradiators

- The irradiator should not be used unless the licensee provides a calibrated and operable radiation survey meter or a room monitor for use with the irradiator.
- The irradiator door should not be opened until the operator has checked visual indicators to verify that the source has returned to its safe storage position.

- Each room monitor should:
 - Be operable at all times when the irradiator is in use
 - Activate a visible and audible alarm when radiation levels exceed 0.02 mSv (2 mrem) per hour
 - Be located to detect any radiation escaping from the irradiator door
 - Be located so that it is visible to the irradiator user when next to the irradiator
- If a room monitor is not installed, a survey meter should be used to:
 - Determine the radiation level at the irradiator door when the door is closed
 - Check for any increase in radiation levels each time the irradiator door is opened. In conducting such checks, operators should position themselves to minimize exposure to any radiation escaping from the open door.
 - If abnormal radiation levels or any malfunction of the irradiator are detected at any time, the licensee should stop using the irradiator, restrict access to the area housing the irradiator, immediately notify the RSO, and determine if a report to DHFS is required.
 - The licensee should not attempt to repair or authorize others to attempt to repair the irradiator except as specifically authorized in a license issued by DHFS.

Elements of Emergency Procedures Applicable to All types of Self-Shielded Irradiators

- Leave the irradiator area (to reduce radiation exposure).
- Control access to the area (e.g., lock door).
- Contact responsible individuals (e.g., names, phone numbers of RSO, irradiator manufacturer (or distributor), emergency response organizations such as fire department, DHFS).
- Take additional steps, dependent on the specific situations (e.g., surveys).
- As appropriate, require timely reporting to DHFS

Changes to Operating and Emergency Procedures Without a License Amendment

Licensees may change their operating and emergency procedures without amending their license if:

- The changes are reviewed and approved by licensee management and the RSO
- Affected licensee staff are trained in the procedures before they are implemented
- The changes are consistent with applicable license conditions and the procedures or commitments submitted in the license application
- The changes do not degrade the safety of the program.

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| Copies of operating and emergency procedures should be provided to all users. Post a current copy at each irradiator's control panel. If posting the operating procedures is not practicable, post a notice describing the document(s) and where it may be examined. |
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Appendix P

Leak Test Program

Training

Before allowing an individual to perform leak testing, the RSO will ensure that he or she has sufficient classroom and on-the-job training to show competency in performing leak tests independently.

Classroom training may be in the form of lecture, videotape, hands-on, or self-study and will cover the following subject areas:

- Principles and practices of radiation protection
- Radioactivity measurements, monitoring techniques, and using instruments
- Mathematics and calculations basic to using and measuring radioactivity
- Biological effects of radiation.

Appropriate on-the-job-training consists of:

- Observing authorized personnel collecting and analyzing leak test samples .
- Collecting and analyzing leak test samples under the supervision and in the physical presence of an individual authorized to perform leak tests.

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, leak tests will be analyzed in a low-background area.
- Individuals conducting leak tests will use a calibrated and operable survey instrument to check leak test samples for gross contamination before they are analyzed. If the sensitivity of the counting system is unknown, the minimum detectable activity (MDA) needs to be determined. The MDA may be determined using the following formula:

$$MDA = \frac{2.71 + 4.65\sqrt{(B_R \times t)}}{t \times E} = \text{Minimum Detectable Activity}$$

where:

| | | |
|----------------|---|---|
| MDA | = | activity level in disintegrations per minute |
| B _R | = | background rate in counts per minute |
| t | = | counting time in minutes |
| E | = | detector efficiency in counts per disintegrations |

For example:

| | | |
|----------------|---|---|
| B _R | = | 200 counts per minute |
| E | = | 0.1 counts per disintegration (10% efficient) |
| t | = | 2 minutes |

$$MDA = \frac{2.71 + 4.65\sqrt{(200 \times 2)}}{2 \times 0.1} = \frac{2.71 + 4.65\sqrt{(400)}}{0.2}$$

$$= \frac{2.71 + 4.65 (20)}{0.2} = \frac{2.71 + 9}{0.2} = \frac{11.71}{0.2}$$

$$= \frac{59 \text{ disintegrations}}{\text{minute}}$$

$$\text{becquerels (Bq)} = \frac{1 \text{ disintegration}}{\text{second}}$$

$$Bq = \frac{59 \text{ disintegrations}}{\text{minutes}} \times \frac{\text{minute}}{60 \text{ seconds}} = 0.98 = 1 \text{ Bq}$$

- A NaI(Tl) well counter system with a single or multi-channel analyzer will be used to count samples from irradiators containing gamma-emitters (e.g., Cs-137, Co-60).
- A liquid scintillation or gas-flow proportional counting system will be used to count samples from irradiators containing beta-emitters (e.g., Sr-90).

Frequency for Conducting Leak Tests of Sealed Sources

- Leak tests will be conducted at the frequency specified in the respective SSD Registration Certificate.

Procedure for Performing Leak Testing and Analysis

- For each source to be tested, list identifying information such as self-shielded irradiator serial number, radionuclide, activity.
- If available, use a survey meter to monitor exposure.
- Prepare a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- Number each wipe to correlate with identifying information for each source.
- Wipe the most accessible area where contamination would accumulate if the sealed source were leaking.
- Select an instrument that is sensitive enough to detect 185 Bq (0.005 microcurie) of the radionuclide in the irradiator.
- Using the selected instrument, count and record background count rate.

- Check the instrument's counting efficiency using a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards should be within $\pm 5\%$ of the stated value and traceable to primary radiation standards such as those maintained by NIST.
- Calculate efficiency.

For example:
$$\frac{[(\text{cpm from std}) - (\text{cpm from bkg})]}{\text{Activity of std in Bq}} = \text{efficiency in cpm/bq}$$

Where:

| | | |
|-----|---|-------------------|
| cpm | = | counts per minute |
| std | = | standard |
| bkg | = | background |
| Bq | = | Becquerel |

- Count each wipe sample; determine net count rate
- For each sample, calculate and record estimated activity in Bq (or microcuries).

For example:
$$\frac{[(\text{cpm from wipe sample}) - (\text{cpm from bkg})]}{\text{Efficiency in cpm/Bq}} = \text{Bq on wipe sample}$$

- Sign and date the list of sources, date and calculations. Retain records for 3 years (*HFS 157.31(3)*).
- If the wipe test activity is 185 Bq (0.005 microcurie) or greater, notify the RSO, so that the source can be withdrawn from use and disposed of properly. Also notify DHFS.

Reference: See Section 8.10.8 and Appendix O of NRC NUREG 1556 Vol. 18 “Program Specific Guidance about Service Provider Licenses,” and is available electronically at NRC’s web site, <http://www.nrc.gov>, under “Electronic Reading Room,” then “All Collections,” the “NUREG-Series Publications.”

Appendix Q

Transportation

Part 1 Major DOT Regulations

The major areas in the DOT regulations that are most relevant for transportation of typical self-shielded irradiators that are shipped as Type A or Type B quantities are as follows:

- Table of Hazardous Materials and Special Provisions **49 CFR 172.101**, and App. A, Table 2: Hazardous materials table, list of hazardous substances and reportable quantities
- Shipping Papers **49 CFR 172.200-204**: general entries, description, additional description requirements, shipper's certification
- Package Markings **49 CFR 172.300, 49 CFR 172.301, 49 CFR 172.303, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.324**: General marking requirements for non-bulk packagings, prohibited marking, marking requirements, radioactive material, hazardous substances in non-bulk packaging
- Package Labeling **49 CFR 172.400, 49 CFR 172.401, 49 CFR 172.403, 49 CFR 172.406, 49 CFR 172.407, 49 CFR 172.436, 49 CFR 172.438, 49 CFR 172.440**: General labeling requirements, prohibited labeling, radioactive materials, placement of labels, specifications for radioactive labels
- Placarding of Vehicles **49 CFR 172.500, 49 CFR 172.502, 49 CFR 172.504, 49 CFR 172.506, 49 CFR 172.516, 49 CFR 172.519, 49 CFR 172.556**: Applicability, prohibited and permissive placarding, general placarding requirements, providing and affixing placards: highway, visibility and display of placards, RADIOACTIVE placard
- Emergency Response Information, Subpart G, **49 CFR 172.600, 49 CFR 172.602, 49 CFR 172.604**: Applicability and general requirements, emergency response information, emergency response telephone number
- Training, Subpart H, **49 CFR 172.702, 49 CFR 172.704**: Applicability and responsibility for training and testing, training requirements
- Radiation Protection Program for Shippers and Carriers, Subpart I, 49 CFR 172.800, etc.
- Shippers - General Requirements for Shipments and Packaging, Subpart I, **49 CFR 173.403, 49 CFR 173.410, 49 CFR 173.411, 49 CFR 173.412, 49 CFR 173.413, 49 CFR 173.415, 49 CFR 173.416, 49 CFR 173.433, 49 CFR 173.435, 49 CFR 173.441, 49 CFR 173.471, 49 CFR 173.475, 49 CFR 173.476**: Definitions, general design requirements, industrial packages, additional design requirements for Type A packages, requirements for Type B packages, authorized Type A packages, authorized Type B packages (including package certification requirements), requirement for determining A_1 and A_2 ..., table of A_1 and A_2 values for radionuclides, radiation level limit, requirements for U.S. NRC-approved packages (Type B), quality control requirements prior to each shipment..., approval of special form radioactive materials
- Carriage by Public Highway, **49 CFR 177.816, 49 CFR 177.817, 49 CFR 177.834(a), 49 CFR 177.842**: Driver training, shipping paper, general requirements (secured against movement), Class 7 (radioactive) material.

Part 2 Sample Bill of Lading

STRAIGHT BILL OF LADING

ORIGINAL—NOT NEGOTIABLE

Shipper No. _____

Carrier No. _____

Page 1 of 1

Name of carrier _____

SCAC _____

Date _____

| | | | |
|--|--|---|--|
| TO: Consignee <u>Irradiator Maker, Inc. **</u> <small>On Collect on Delivery shipments, the letters "COD" must appear before consignee's name or as otherwise provided in Item 430, Sec. 1.</small> | | FROM: Shipper <u>Irradiation Studies, Inc. **</u> | |
| Street <u>4321 Broad Street **</u> | | Street <u>1234 A Street, NW **</u> | |
| Destination <u>Somewhere USA **</u> Zip Code <u>12345**</u> | | Origin <u>Washington, DC 20001 **</u> | |

| Route | | Vehicle Number | | | | |
|-------------------------------|----|--|---|----------------------------------|------|-----------------------------------|
| No. of Units & Container Type | HM | BASIC DESCRIPTION (Proper Shipping Name, Hazard Class, Identification Number, etc.) | TOTAL QUANTITY (Weight, Volume, Gallons, etc.) | WEIGHT (Shipped to Consignee) | RATE | CHARGES (For Carrier Use Only) |
| 1 | RQ | Radioactive material, special form, n.o.s., 7, UN2974 100 TBq Cs-137 ** | 100 TBq ** | | | |
| | | RADIOACTIVE - YELLOW (I) ** | | | | |
| | | TJ = 0.4 ** | | | | |
| | | USA/1234/B(U) Type B Container ** | | | | |
| | | Emergency Response Telephone No. 1-800-000-0000 (24 hr/d) ** | | | | |
| | | ** SUBSTITUTE APPROPRIATE INFORMATION FOR YOUR SHIPMENT | | | | |
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PLACARDS TENDERED: YES ☐ NO ☒

REMIT
C.O.D. TO:
ADDRESS

COD

Amt: \$

C.O.D. FEE:
PREPAID ☐
COLLECT ☐

TOTAL CHARGES: \$

FREIGHT CHARGES

Freight prepaid ☐ Freight collect ☐

Note: Where the rate is dependent on value, shippers are required to state specifically in writing the agreed or declared value of the property.

The agreed or declared value of the property is hereby specifically stated by the shipper to be not exceeding:

\$ _____

I hereby declare that the contents of this consignment are fully and accurately described above by proper shipping name and are classified, packaged, marked and labeled and are in all respects in proper condition for transport by rail, highway, water (DELETE FROM APPLICABLE BOOK OF TRANSPORT) according to applicable international and national governmental regulations.

John J. ... Signature

Subject to Section 7 of the conditions, if this shipment is to be delivered to the consignee without recourse on the consignment, the consignee shall sign the following statement:

The carrier shall not make delivery of this shipment without payment of freight and all other duties charges.

Signature of Consignee _____

RECEIVED: subject to the classification and identification, clarity in effect on the date of the issue of this Bill of Lading, the property described above in apparent good order except as noted on the bill and condition of contents of packages, unknown, marked, consigned and delivered as indicated above which said carrier, the said carrier being understood throughout this contract as meaning any person or corporation in possession of the property, under the contract, agrees to carry to its usual place of delivery at said destination, if on its route, otherwise to deliver to another carrier on the route to said destination. It is mutually agreed as to each carrier or all or any of said property over all or any portion of

said route to destination and as to each party at any time interested in all or any said property that every service to be performed hereunder shall be subject to all the bill of lading terms and conditions in the governing classification on the date of shipment.

Shipper hereby certifies that he is familiar with all the bill of lading terms and conditions in the governing classification and the said terms and conditions are hereby agreed to by the shipper and accepted by himself and his design.

SHIPPER

CARRIER

PER

Q-3

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Part 3. Irradiators Built Before 1966

Before the adoption of the requirements of 10 CFR Part 71 in 1966, irradiators could be transported without being evaluated under the hypothetical accident conditions now incorporated in 10 CFR Part 71. Unlike most post-1966 irradiators, pre-1966 irradiations are not certified shipping packages. Transport of pre-1966 units may require transferring the sealed source from the irradiator to a Type B package or use of a certified package for the irradiator containing the sealed sources.

DHFS will consider a licensee's request for an exemption for a one-time shipment according to ***HFS 157.04(1)*** only if these options are not viable.

An exemption may be granted if the request is authorized by law and will not endanger life or property or the common defense and security. In this case, an exemption request should demonstrate the need for the exemption, describe why alternatives considered are not viable, specify from what requirement(s) an exemption is requested and the period for which the exemption is requested, and describe steps taken to ensure that the shipment will not endanger life or property or the common defense and security (e.g., steps to minimize accident risk and to respond to a transportation accident). Typically, approved requests are for a limited period (e.g., 30 days).

Circumstances vary, but additional information supporting an exemption request may include the following:

- Manufacturer's (or distributor's) name and model number of the irradiator, the type and activity of radioactive material to be transported, and brief description of proposed trip (starting and ending points and approximate distance)
- Engineering drawings of irradiator
- Consideration of the following:
 - DOT's hazardous material routing requirements
 - Transport during time of low road usage
 - Use of good roads and avoidance of residential areas to maximum extent possible
 - Accompaniment of shipment by escort knowledgeable in the use of radiation survey instruments
 - Provision of escort with appropriate survey instruments and supplies to permit the establishment of a radiation exclusion area
 - Written procedures to be followed by the escort in an emergency situation.
 - Use of exclusive-use vehicle and shoring to limit movement of package during transport

- Notification of State radiological health officials and local fire department of time and route of shipment.
- Planned date of shipment

Before applying to DHFS for its approval, the licensee should contact other states radiological health organizations within each State through which the shipment will be made to confirm the points of contact and to discuss the proposed controls for the shipment.

DHFS reserves the right to accompany a shipment of an irradiator.

DHFS must review these requests, which are typically requests to amend materials (**Chapter HFS 157 ‘Radiation Protection’, Subchapter II ‘Licensing of Radioactive Material’**) licenses. Licensees should address their requests to:

*Department of Health and Family Services
Radiation Protection Section
P.O. Box 2659
Madison, WI 53701-2659*

In addition to a DHFS exemption, the licensee may also need a DOT exemption; contact DOT's Office of Hazardous Materials Technology at 202-366-4545 for additional information.

The response from the licensee for the exemption must demonstrate that the request is authorized by law and will protect public health and safety. It must also include the following information:

- Establish that the irradiator was built before 1966.
- Explain why an approved package cannot be used, the alternatives considered, and why each is not viable.
- Specify from what requirement(s) an exemption is requested and the period for which the exemption is requested.
- Describe procedures, controls, and other actions to be taken to ensure that the shipment will not endanger life or property or the common defense and security.

Reference: The names, addresses, and telephone numbers for officials in Agreement and Non-Agreement States are available by choosing ‘Directories’ on the NRC’s OSP Home Page at <http://www.hsrdrnrl.gov/nrc/home.htm>. As an alternative, contact DHFS at (608) 267-4797, during office hours.